PATENT
Docket No. 290.00420101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	Shi et al.	Group Art Unit:	1617
Serial No.:	09/438,206	Examiner:	Hui
Confirmation No.:	9018		
Filed:	12 November 1999		

For: METHODS AND COMPOSITIONS FOR TREATING MAMMALIAN SPINAL CORD INJURIES

APPEAL BRIEF

Commissioner for Patents
Mail Stop Appeal Brief - Patents
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Sir:

This Brief is presented in support of the Appeal filed June 23, 2005, from the rejection of claims 22-30, 38-40, 43, and 44 of the above-identified application under 37 C.F.R. §§1.113 and 1.191.

This Brief is being submitted as set forth in 37 C.F.R. § 41.37. Please charge Deposit Account No. 13-4895 the fee for filing this Brief under 37 C.F.R. § 41.20(b)(2).

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I. REAL PARTY IN INTEREST

The real party in interest of the above-identified patent application is the assignee, Purdue Research Foundation, Office of Technology Commercialization, as evidenced by the assignment recorded at Reel 010613, Frame 0289 on 15 February 2000.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to Appellants' Representatives which would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-21, 31-37, 41, and 42 having been canceled, the pending claims are claims 22-30, 38-40, 43, and 44. Rejected claims 22-30, 38-40, 43, and 44 are the subject of this Appeal (see Claim Appendix).

IV. STATUS OF AMENDMENTS

A Request for Continued Examination (RCE) under 37 CFR 1.114 and an Amendment and Response were filed on November 24, 2004. Amendments to claims 22 and 38 filed with the RCE have been entered pursuant to the nonfinal Office Action mailed February 23, 2005. No claim amendments have been made subsequent to the nonfinal Office Action mailed February 23, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

For the purposes of this appeal, a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided below. These explanations are not intended and should not be used to limit the scope of the claims. Reference to description within the specification is merely exemplary and does not imply that the example provided is the only example available.

Claim 22: A Method of Treating a Mammalian Patient Having Suffered an Injury to its Spinal Cord

Independent claim 22 recites a method of treating a mammalian patient having suffered an injury to its spinal cord (e.g., page 3, lines 3-6 and page 11, lines 11-12 of the specification), the method including contacting the injured spinal cord after the injury but within a period no greater than about 24 hours after said injury (e.g., page 12, lines 26-29 of the specification) with a composition including an effective amount of at least one C1-C10 polyalkylene glycol (e.g., page 11, line 29 to page 12, line 2 of the specification), wherein the effective amount of at least one C1-C10 polyalkylene glycol is effective to restore nerve impulse conduction through said injured spinal cord (e.g., page 14, lines 25-31, page 46, lines 6-9, and Examples 5 and 6 from pages 37-46 of the specification).

Claim 38: A Method of Treating a Mammalian Patient Having Suffered an Injury to its Spinal Cord

Independent claim 38 recites a method of treating a mammalian patient having suffered an injury to its spinal cord (e.g., page 3, lines 3-6 and page 11, lines 11-12 of the specification), the method including contacting the injured spinal cord after the injury but within a period no greater than about 24 hours after said injury (e.g., page 12, lines 26-29 of the specification) with a composition including an effective amount of polyethylene glycol (e.g., page 3, lines 13-14 and page 12, lines 3-4 of the specification), wherein the effective amount of polyethylene glycol is effective to restore nerve impulse conduction through said injured spinal cord (e.g., page 14, lines 25-31 page 46, lines 6-9, and Examples 5 and 6 from pages 37-46 of the specification).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A1. Claims 22-30, 38, 40, and 44 stand rejected under 35 U.S.C. §112, first paragraph, as claiming subject matter not enabled by the specification.

A2. Claims 22-30, 38, 40, 43, and 44 stand rejected under 35 U.S.C. §112, first paragraph, as claiming subject matter not enabled by the specification.

B. Claims 22-29, 38, and 39 stand provisionally rejected under the judicially created

doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/132,542.

C. Claims 22, 24-30, 38-40, 43, and 44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Balasubramanian (U.S. 5,382,584) in view of Potter et al. (Clin Invest Med, 19(4), Suppl.:S80, #533).

D. Claims 22-30, 38-40, 43, and 44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shulman (U.S. 4,599,354) in view of Edwards (U.S. 4,369,769).

VII. ARGUMENT

A1. Claims 22-30, 38, 40, and 44 are enabled by the specification; they meet the requirements of 35 U.S.C. §112, first paragraph.

Claims 22-30, 38, 40, and 44 stand rejected under 35 U.S.C. §112, first paragraph. In rejecting claims 22-30, 38, 40, and 44, the Examiner asserted, that while being enabling for polyethylene glycol ("PEG") with a molecular weight of 40 to 3500 daltons, "the specification does not reasonably provide enablement for PEG 4000. The specification does not enable any person skilled in the art to which it pertains, or is most nearly connected, to use the invention commensurate with the scope of the claims" (pages 2-3, Office Action mailed February 23, 2005). Appellants respectfully disagree and request review and reversal of this rejection by the Board.

Claims 22-30, 38, 40, and 44 are drawn to a method of treating a mammalian patient having suffered an injury to its spinal cord, comprising contacting the injured spinal cord . . . with a composition comprising an effective amount of at least one C1-C10 polyalkylene glycol (claims 22-30 and 44) or polyethylene glycol (claims 38, 40, and 44), wherein the effective amount of at least one C1-C10 polyalkylene glycol or polyethylene glycol is effective to restore nerve impulse conduction through the injured spinal cord.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). And, "the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the

specification to persons of ordinary skill in the art." *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1005 (Fed. Circ. 1997).

Appellants respectfully submit that claims 22-30, 38, 40, and 44 as a whole are enabled by the specification. The specification teaches that "a wide range of molecular weights of polyalkylene glycols may be used" (page 12, lines 4-5 of the specification) and that "a physiological, balanced media and the aforementioned PEG solution is all that is required to produce functionally significant repair in mammalian spinal cords" (page 27, lines 3-5 of the specification). Moreover, the specification teaches that "no specific PEG molecular weight [is] critical to the process," (page 27, lines 7- 8 of the specification), with PEG solutions of 400, 1400, 1800, 2000, and 3700 daltons producing functionally significant repair in injured mammalian spinal cords (page 27, lines 3-9 of the specification), and functional fusion results obtained using 1400, 1800, 2000, and 3500 dalton PEG (page 31, lines 28-31 of the specification). Appellants respectfully submit that the specification enables any person skilled in the art to which it pertains, or is most nearly connected, to make and use the invention commensurate with the full scope of the claims.

Further, Appellants respectfully submit that the particular embodiments cited by the Examiner are not, as alleged by the Examiner, inoperable. To support the assertion that the "employment of PEG 4000 is not enabled by the instant specification" (page 3, Office Action mailed February 23, 2005), the Examiner references the observations of Selby (Letter to the Editor, Neurosurgery 1983;12:591). Selby presents "initial observation[s] . . . that both Depo-Medrol (methylprednisolone acetate suspensions . . .) and its sterile vehicle, polyethylene glycol 4000, can immediately result in the dissolution of myelin and may cause manifestations of the loss of neural function. . . . Because of these findings it may be worthwhile to avoid the use of Depro-Medrol in and about any nervous elements . . . until this matter is resolved." Appellants respectfully submit that the observations of Selby, of the dissolution of myelin, and concerns of a possible loss of neural function with the application of Depro-Medrol containing PEG 4000, do not reasonably establish a lack of enablement for the use PEG 4000 in the methods of claims 22-30, 38, 40, and 44, drawn to methods of treating a mammalian patient having suffered an injury to its spinal cord with the application of a biomembrane fusion agent (at least one C1-C10

polyalkylene glycol in claims 22-30 and 44; polyethylene glycol in claims 38, 40, and 44).

Finally, Appellants submit that even if Selby teaches away from the use of a particular formulation, claims 22-30, 38, 40, and 44 are still fully enabled by the specification. Moreover, the law is clear that "[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art." MPEP § 2164.08(b) (*see also, Atlas Powder Co. v. E.I. du Pont de Nemors & Co.*, 750 F.2d 1569, 1577, 244 USPQ 409, 414 (Fed Cir. 1984)). Applicants submit that it would involve only routine experimentation and not undue experimentation on the part of the skilled person, using the specification for guidance along with the knowledge in the art, to recognize that a specific formulation fall within the scope of the invention, as claimed. Applicants submit that "[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances" (*In re Dinh-Nguyen*, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted)) and claims 22-30, 38, 40, and 44 are fully enabled by the specification.

In conclusion, Appellants respectfully submit that the specification enables any person skilled in the art to which it pertains, or is most nearly connected, to make and use the invention commensurate with the scope of the claims. Review and reversal of this rejection by the Board is respectfully requested.

A2. Claims 22-30, 38, 40, 43, and 44 are enabled by the specification; they meet the requirements of 35 U.S.C. §112, first paragraph.

Claims 22-30, 38, 40, 43, and 44 stand rejected under 35 U.S.C. §112, first paragraph, as the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate with the scope of the claims (page 3, Office Action mailed February 23, 2005). Specifically, the Examiner asserted, that while being enabling for 3-10% polyethylene glycol (PEG), the specification does not reasonably provide enablement for 20-40% PEG (page 3, Office Action mailed February 23, 2005). Appellants respectfully disagree and request review and reversal of this rejection by the Board.

Claims 22-30, 38, 40, 43, and 44 are drawn to a method of treating a mammalian patient having suffered an injury to its spinal cord, comprising contacting the injured spinal cord . . . with a composition comprising an effective amount of at least one C1-C10 polyalkylene glycol (claims 22-30 and 44) or polyethylene glycol (claims 38, 40, 43, and 44), wherein the effective amount of at least one C1-C10 polyalkylene glycol or polyethylene glycol is effective to restore nerve impulse conduction through the injured spinal cord.

Appellants respectfully submit that claims 22-30, 38, 40, 43, and 44 as a whole are enabled by the specification and that the Examiner's assertion that the specification does not provide enablement for the use of PEG solutions of greater than 3-10% PEG, by weight, is incorrect. Appellants direct the Board's attention to page 12, lines 20-23 of the specification and Examples 1-3, 5, and 6. Page 12, lines 20-23 of the specification states that "[a]lthough the percentage by weight of the fusion agent in the composition may vary, the composition typically includes at least about 40% of the fusion agent by weight, more preferably about 40% to about 50% by weight, and most preferably about 50% to about 55% by weight." Examples 1-3, 5, and 6 demonstrate the effectiveness of a 50% PEG solution, by weight, in restoring nerve impulse conduction to injured spinal cord. In Examples 1-3, the in vitro application of a 50% by weight solution of polyethylene glycol (PEG) in distilled water (page 19, lines 22-23 of the specification, page 25, lines 1-2, and page 30, lines 21-23) to injured spinal cord results in the restoration of nerve impulse conduction through the injured spinal cord (see, for example, page 16, lines 19-20, page 26, line 22 bridging page 27, line 2, and page 28, lines 26-28 of the specification). In Examples 5 and 6 (pages 37-46 of the specification), the in vivo application of an aqueous solution of PEG, 50% by weight in distilled water (page 38, lines 9-10 of the specification), to injured spinal cords results in the recovery of nerve impulse conduction and a progressive recovery of behavioral functioning of the cutaneous trunci muscle (CTM) reflex (page 46, lines 6-10 of the specification). Appellants respectfully submit that the specification demonstrates the effectiveness of PEG solutions of greater than 3-10% PEG, by weight. Appellants further submit that the specification enables any person skilled in the art to which it pertains, or is most nearly connected, to make and use the invention commensurate with the full scope of the claims.

Still further, Appellants submit that the particular embodiments cited by the Examiner are

not inoperable. The Examiner asserted that "in view of teachings of Benzon et al. . . . 20-40% PEG will result in slowing the conduction velocity of the nerve. Therefore, the employment of 20-40% PEG is not enabled by the instant specification" (page 3, Office Action mailed February 23, 2005). Appellants respectfully disagree.

Briefly, Benzon et al. (Anesth. Analg. 66:553-59, 1987) examined the effect of 3%, 10%, 20%, 30%, and 40% PEG solutions on nerve impulse transmission in healthy nerve fibers (page 556 of Benzon et al.). Benzon et al. concluded, that while 3% PEG does not have a deleterious effect on nerve transmission (page 557, column 1, and page 558, column 2 of Benzon et al.), higher concentrations of PEG (20-30%) cause mild to moderate slowing of the conduction of nerve transmission, and exposure to a 40% PEG solution for one hour results in a complete block of nerve transmission (see page 558, column 2 of Benzon et al.). In contrast to the teachings of Benzon et al., of the effect of PEG on nerve conduction in *healthy nerve fibers*, claims 22-30, 38, 40, 43, and 44 are drawn to the treatment of *spinal cord injuries* including contacting *the injured spinal cord* with a composition including at least one C1-C10 polyalkylene glycol (claims 22-30 and 44) or with a composition including polyethylene glycol (claims 38, 40, 43, and 44) in an amount effective to *restore nerve impulse conduction through the injured spinal cord.*

Appellants submit that the showings of Benzon et al. of the effect of PEG on nerve conduction in healthy nerve tissues are not relevant to the methods of claims 22-30, 38, 40, 43, and 44, which are directed to methods of treating spinal cord injuries so that nerve impulse conduction is restored through the spinal cord injury.

Finally, Appellants submit that although the particular embodiment cited by the Examiner is not inoperable, even if this particular embodiment were to be inoperable, claims 22-30, 38, 40, 43, and 44 are still fully enabled by the specification. As discussed in more detail in section A1, above, "[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled" (MPEP 2164.08(b)) and "[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances" (*In re Dinh-Nguyen*, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted)). Applicants submit that it would involve only routine experimentation and not undue experimentation on the part of the skilled person, using the specification for guidance, to recognize if specific concentrations of

PEG presented as an inoperative embodiment. Applicants submit that and that claims 22-30, 38, 40, 43, and 44 are fully enabled by the specification.

In conclusion, Appellants respectfully submit that the specification enables any person skilled in the art to which it pertains, or is most nearly connected, to make and use the invention commensurate with the scope of the claims. Review and reversal of this rejection by the Board is respectfully requested.

B. Withdrawal of the provisional rejection of claims 22-29, 38, and 39 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/132,542 is requested in view of Terminal Disclaimer submitted herewith.

Claims 22-29, 38, and 39 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/132,542 (page 3-4, Office Action mailed February 23, 2005). Submitted herewith is a Terminal Disclaimer which, Applicants submit, is in compliance with 37 CFR 1.321(c) and thereby obviates the Examiner's double patenting rejection of pending claims 22-29, 38, and 39. Appellants respectfully request that this rejection be withdrawn.

C. Claims 22, 24-30, 38-40, 43, and 44 are patentable under 35 U.S.C. §103(a) over Balasubramanian (U.S. 5,382,584) in view of Potter et al. (Clin Invest Med, 19(4), Suppl.:S80, #533).

Claims 22, 24-30, 38-40, and 43-44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Balasubramanian (U.S. Patent No. 5,382,584) in view of Potter et al. (Clin. Invest Med, 1996;19(4) Suppl. S80 #533) (pages 4-7, Office Action mailed February 23, 2005). Appellants request review and reversal of this rejection by the Board.

Appellants respectfully submit that the Examiner has not met the burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three criteria must be met. First, the prior art reference (or references) must teach or suggest all of the claim limitations. Second, there must be some suggestion or motivation, either in the cited reference (or references), or in the knowledge generally available to one of ordinary skill in the art, to

modify the reference or combine reference teachings. Third, there must be a reasonable expectation of success. MPEP § 2142 (*see also*, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Claim 22 (as well as dependent claims 23-30 and 44) is drawn to a method of treating a mammalian patient having suffered an injury to its spinal cord with a composition comprising an effective amount of at least one C_1-C_{10} polyalkylene glycol, wherein the effective amount of at least one C_1-C_{10} polyalkylene glycol is effective to restore nerve impulse conduction through said injured spinal cord. Claim 38 (as well as dependent claims 39, 40, 43, and 44) is drawn to a method of treating a mammalian patient having suffered an injury to its spinal cord with a composition comprising an effective amount of polyethylene glycol, wherein the effective amount of polyethylene glycol is effective to restore nerve impulse conduction through said injured spinal cord. Dependent claim 30 is drawn to the "method according to claim 22 . . . wherein said method further comprises the step of contacting said injured spinal cord with a synergistic amount of 4-aminopyridine" and dependent claims 40 and 43 are drawn to the "method according to claim 38 further comprising the step of contacting said injured spinal cord with a potassium channel blocker in the form of 4-aminopyridine."

Balasubramanian teaches that a series of compounds that are 1-piperazinyl-N-phenylacetamide derivatives of 4,5-diphenyl-oxazoles, thiazoles, and imidazoles were found to provide effective antiischemic protection for central nervous system and cardiac tissue, particularly neurons (Abstract). The compounds were described as novel adenosine reuptake inhibitors (column 1, lines 19-22). The only teachings in Balasubramanian making reference to the use of polyethylene glycol are found in the paragraph bridging columns five and six, which states that polyethylene glycol may be used as a *lubricant* when administering the active ingredient in tablet or capsule form (column 6, lines 4-11 (emphasis added)); or as a *vehicle* for the parenteral administration of an active compound (column 6, lines 12-23 (emphasis added)).

Potter discusses 4-aminopyridine as a K^+ channel blocking agent that enhances nerve conduction through areas of demyelination in patients with spinal cord injuries.

Balasubramanian in view of Potter does not teach or suggest all of the limitations of the claimed methods of treating spinal cord injuries.

Appellants submit that Balasubramanian considered alone or in combination with Potter does not teach or suggest all of the limitations of the claimed methods of treating spinal cord injuries. The methods of claims 22-20, 38-40, 43, and 44 are methods of treating spinal cord injuries by contacting the injured spinal cord with *an effective amount* of "at least one C_1-C_{10} polyalkylene glycol" (claims 22-30 and 44) or "polyethylene glycol" (claims 38-40, 43 and 44), *wherein the effective amount* of the at least one C_1-C_{10} polyalkylene glycol or the polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord.* Balasubramanian teaches polyethylene glycols for use as non-toxic, inert, and pharmaceutically acceptable carriers (column 5, lines 20-23) in the preparation of pharmaceutical compositions of adenosine reuptake inhibitors. Balasubramanian does not teach or suggest the restoration of nerve impulse conduction through a spinal cord injury. Balasubramanian does not teach or suggest that the administration of polyethylene glycol is effective to treat spinal cord injuries and, thus, does not teach the administration of *an effective amount* of polyethylene glycol, *wherein the effective amount* of polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord.* Thus, Appellants submit that Balasubramanian does not teach or suggest all the limitations of the claimed methods. This deficiency is not corrected by Potter, which is silent as to the use of polyethylene glycol or C1-C10 polyalkylene glycols. Balasubramanian in view of Potter does not teach or suggest all of the limitations of the claimed methods of treating spinal cord injuries.

The Examiner asserted that the "claims are directed to a method of treating spinal cord injuries comprising polyalkylene glycol. . . . Therefore, a method of treating spinal cord injuries as herein recited encompasses the method of treating spinal cord injuries by employing any polyethylene glycol composition" (page 8, Office Action mailed February 23, 2005 (emphasis in original)). Appellants respectfully submit that the Examiner has failed to read the claims as a whole and has oversimplified the claimed methods. The Federal Circuit made the following elementary observation about patent claims, "each claim is an *entity* which must be considered as a *whole*. It cannot be said–though it often is, incorrectly, by the uninitiated–that a part of a claim is 'claimed' subject matter." *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d

1272, 1274, 23 USPQ2d 1839, 1840 (Fed Cir. 1992) (emphasis in original). Considered as a whole, the claimed methods do not encompass, as asserted by the Examiner, "treating spinal cord injuries by employing any polyethylene glycol composition." Rather, as discussed above, claims 22-20, 38-40, 43, and 44 are drawn to methods of treating spinal cord injuries by contacting the injured spinal cord with *an effective amount* of "at least one C_1-C_{10} polyalkylene glycol" (claims 22-30 and 44) or "polyethylene glycol" (claims 38-40, 43 and 44), *wherein the effective amount* of the at least one C_1-C_{10} polyalkylene glycol or the polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord.*

Appellants respectfully submit that Balasubramanian in view of Potter does not teach contacting an injured spinal cord with *an effective amount* of at least one C_1-C_{10} polyalkylene glycol or polyethylene glycol, *wherein the effective amount* of the at least one C_1-C_{10} polyalkylene glycol or the polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord.* The Examiner has previously found this argument unpersuasive, asserting that "[t]he arguments are directed to the effects PEG supposed (*sic*) to produce; however, examiner notes that the limitation recited in the claims are directed to the amount of PEG, which is met by the cited prior arts. Therefore, the cited prior arts still render the instant claims obvious" (page 8 of Office Action mailed February 23, 2005). Appellants do not understand the basis of these statements. Further, Appellants submit that the cited references (Balasubramanian in view of Potter) does not teach the administration of an effective amount of at least one C_1-C_{10} polyalkylene glycol or polyethylene glycol to an injured spinal cord, wherein the effective amount of the at least one C_1-C_{10} polyalkylene glycol or the polyethylene glycol is effective to restore nerve impulse conduction through said injured spinal cord. Therefore, Balasubramanian in view of Potter does not render the claimed invention obvious.

There is no suggestion or motivation to combine the disclosure of Balasubramanian with the disclosure of Potter.

Appellants further submit that the Examiner has failed to establish the existence of a motivation to combine the cited references. Indeed, there is no suggestion or motivation to combine the disclosure of Balasubramanian with that of Potter. Neither Balasubramanian nor Potter recognizes that PEG is effective for the treatment of spinal cord injuries or that the

administration of PEG is effective to restore nerve impulse conduction through the injured spinal cord. Balasubramanian is directed to the administration of compounds that are adenosine reuptake inhibitors to provide effective antiischemic protection for the central nervous system and cardiac tissue. The limited teachings found in Balasubramanian pertaining to polyethylene glycol are very clearly directed to the use of polyethylene glycols as non-toxic, inert, pharmaceutically acceptable carriers (see column 5, lines 15-23 and column 6, lines 10-11 and lines 22-23). Potter, on the other hand, describes the administration of 4-aminopyridine as a K+ channel blocking agent, for the treatment of nerve conduction defects due to demyelination.

Citing *In re Kerkhoven* (626 F.2d 846, 205 USPQ 1069 (CCPA 1980)), the Examiner asserted that the motivation to combine is found in the teachings of both Balasubramanian and Potter, "that both agents are known to be useful in treating spinal cord injuries. Therefore, absent evidence to the contrary, employing them concomitantly for treating the very same condition, spinal cord injuries, would be obvious" and an additive effect would be reasonably expected (page 7 and 9, Office Action mailed February 23, 2004). Appellants strongly disagree and respectfully submit that the Examiner is misapplying the holding of *In re Kerkhoven*. With *In re Kerkhoven*, the court held that "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be *useful for the same purpose*, in order to form a third composition which is to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art" *(In re Kerkhoven* 626 F.2d 846, 850 205 USPQ 1069, 1072 (CCPA 1980). First, Appellants submit that the holding of *In re Kerkhoven* pertains to compositions and is not relevant to the claimed methods of treatment. Further, Appellants submit that Balasubramanian in view of Potter does not each teach compositions which are *useful for the same purpose*. Rather, Balasubramanian makes a passing reference to compositions including polyethylene glycol as an inert carrier. Potter teaches compositions of 4-aminopyridine for the treatment of nerve demyelination. These are distinctly different purposes. One of ordinary skill in the art would not be motivated to combine the teachings of Balasubramanian with the teachings of Potter to obtain the method of claims 22-30, 38-40, 43, and 44 directed to treating a mammalian patient having suffered an injury to its spinal cord, comprising contacting the injured spinal cord with a composition comprising an

effective amount of at least one C1-C10 polyalkylene glycol (claims 22-30 and 44) or polyethylene glycol (claims 38, 40, 43, and 44), wherein the effective amount of at least one C1-C10 polyalkylene glycol or polyethylene glycol is effective to restore nerve impulse conduction through the injured spinal cord.

There is not a reasonable expectation of success in combining the disclosure of Balasubramanian with the disclosure of Potter.

Appellants further submit that the Examiner has failed to establish the existence of a reasonable expectation of success in combining the disclosure of Balasubramanian with that of Potter. In short, Balasubramanian considered alone or in combination with Potter, fails to teach that polyethylene glycol or a C1-C10 polyalkylene glycol is *effective* to treat spinal cord injuries. Thus, Appellants submit that there is not a reasonable expectation of success in combining the teachings of Balasubramanian with that of Potter.

Further, Appellants submit that references already of record clearly teach away from the present invention and therefore also argue against a reasonable expectation of success. Indeed, the state of the art, prior to Appellants' invention, was such that some skilled in the art discouraged the inclusion of polyethylene glycol in compositions for treating spinal cord injuries. The Board is directed to Selby (Letter to the Editor, Neurosurgery 1983;12:591) and Benzon et al. (Anesth. Analg. 66:553-59, 1987), both of which demonstrate the ineffectiveness of polyethylene glycol for the treatment of spinal cord injuries. In fact, by teaching that the administration of polyethylene glycol is harmful to nervous tissues, both Selby and Benzon et al. teach away from administering polyethylene glycol for the treatment of spinal cord injuries.

Selby warns that the administration of both Depo-medrol® (methylpredisolone acetate suspensions) and its sterile vehicle, polyethylene glycol 4000 (including administration to intrathecal nerve roots), "can immediately result in the dissolution of myelin and may cause manifestations of the loss of neural function." Selby recommends that, "[b]ecause of these findings, it may be worthwhile to avoid the use of Depo-Medrol in and about nervous elements" (Selby, Neurosurgery 1983;12:591).

Benzon et al. note that polyethylene glycols "are heat stable and chemically inert. Their

low systemic toxicity, wide range of drug capabilities, and exceptional solubilization characteristics make them useful as vehicles for drugs," including methylpredisolone acetate (page 556 of Benzon et al.). However, Benzon et al., in discussing reports of neurodysfunction associated with injections of methylpredisolone acetate, point out that "it has been postulated that the PEG vehicle is the offending agent," and teach that "[t]he occurrence of neurologic complications after intrathecal steroid injection has been ascribed to PEG" (see abstract, page 553, and page 556 of Benzon et al.) Benzon et al. examined the neurotoxic effect of 3%, 10%, 20%, 30%, and 40% PEG solutions, looking at the depression or abolition of nerve transmission as a measure of neurotoxicity (page 556 of Benzon et al.). Benzon et al. concluded, that while 3% PEG, the concentration used clinically as an inert carrier, does not have a deleterious effect on nerve transmission (page 557, column 1, and page 558, column 2 of Benzon et al.), higher concentrations of PEG (20-30%) cause mild to moderate neurotoxicity, and exposure to a 40% PEG solution results in a complete block of nerve transmission (see page 558, column 2 of Benzon et al.).

Appellants submit that the teachings of Selby and Benzon et al. express concerns over the harmful effects of administering polyethylene glycol to nervous tissue, thereby teaching away from combining the teachings of Balasubramanian and Potter, and away from the claimed invention. Appellants submit that there is no reasonable expectation of success in combining the teachings of Balasubramanian with that of Potter.

The Examiner has failed to consider unexpected results.

In addition, Appellants submit that even if, assuming for the sake of argument, the Examiner had established a *prima facie* case for the unpatentability of that claims 22, 24-30, 38-40, and 43-44 under 35 U.S.C. §103(a) over Balasubramanian in view of Potter et al., which he has not, the Examiner has failed to recognize and consider the unexpected results achieved in the methods of claims 30, 40, and 43. In this regard, Appellants direct the Examiner's attention to page 13, line 26 to page 14, line 2 of the specification, which clearly teaches that "it has unexpectedly been observed that treatment of the injured mammalian spinal cord with a potassium channel blocker, such as 4-aminopyridine, after treatment with a fusion agent, such as

polyethylene glycol, can result in synergistic repair of the spinal cord. For example, CAPs increase in conduction when both agents are used by a percentage greater than the sum of the percent increase in conduction of the CAPs when injured spinal cords are treated alone with either the fusion agent or the potassium channel blocker." Thus, treatment with both a fusion agent and a potassium channel blocker is not merely additive and claims 30, 40, and 43 cannot be obvious over the combined teachings of Balasubramanian and Potter.

In conclusion, Appellants submit that the Examiner has not met the burden of establishing a *prima facie* case for the aforementioned reasons, and moreover, has not established that the invention, as claimed, is rendered obvious. Accordingly, reversal of this rejections of the claims under 35 U.S.C. § 103 is respectfully requested.

D. Claims 22-30, 38-40, 43, and 44 are patentable under 35 U.S.C. §103(a) over Shulman (U.S. Patent No. 4,599,354) in view of Edwards (U.S. Patent No. 4,369,769).

Claims 22-30, 38-40, 43, and 44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shulman (U.S. Patent No. 4,599,354) in view of Edwards (U.S. Patent No. 4,369,769) (pages 10-11, Office Action mailed February 23, 2005). Appellants request review and reversal of this rejection by the Board.

Appellants respectfully submit that the Examiner has not met the burden of establishing a *prima facie* case of obviousness. Appellants submit that Shulman in view of Edwards does not teach or suggest all of the claim limitations. Further, Appellants submit that the requisite suggestion or motivation to combine the teachings of Shulman and Edwards is not found either in the cited references or in the knowledge generally available to one of ordinary skill in the art. Thus, claims 22-30, 38-40, 43, and 44 are not obvious under 35 U.S.C. §103(a) over Shulman in view of Edwards.

Claims 22-20, 38-40, 43, and 44 are drawn to a method of treating spinal cord injuries by contacting the injured spinal cord with *an effective amount* of "at least one C_1-C_{10} polyalkylene glycol" (claims 22-30 and 44) or "polyethylene glycol" (claims 38-40, 43 and 44), *wherein the effective amount* of the at least one C_1-C_{10} polyalkylene glycol or the polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord.*

The Examiner asserted that "Shulman teaches a[n] extended epidural pain relief composition containing 2.3% of PEG or with molecular weight of 1000-5000," and that "Shulman also teaches . . . selecting the PEG that is non-toxic in a concentration required to perform the suspending function." The Examiner also asserted that while "Shulman does not expressly teach the epidural pain relief composition as useful in treating spinal cord injury[,] Edwards teaches that spinal cord fracture and injury always cause pain." Thus, the Examiner asserted "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the PEG containing composition of Shulman in the treatment of spinal cord fractures and injuries." Page 10 Office Action mailed February 23, 2005.

Appellants respectfully disagree. Shulman teaches "[a] composition and method for producing lasting pain relief in a body by injection. The composition consists essentially of a sterile, stable suspension of butyl aminobenzoate in a non-toxic, aqueous carrying medium in which the butyl aminobenzoate is insoluble" (Abstract). "The aqueous carrying medium consists essentially of a high molecular weight, water insoluble suspension agent for butyl amino benzoate, and water" (column 2, lines 42-45). Butyl amino benzoate is a local anesthetic, characterized by its poor solubility in water (column 1, lines 21-24 and column 7, lines 23-25). "A typical suspension agent is polyethylene glycol having a molecular weight in the range of 1000-5000" (column 2, lines 46-49). Thus, Shulman teaches polyethylene glycol solely as a suspending agent in a composition to be injected for pain relief. The composition

> produces lasting pain relief in a body region by injection of the suspension around a nerve proximal to a body region where pain relief is desired. . . . Upon injection, the suspension releases the butyl aminobenzoate relatively slowly to give pain relief typically lasting several weeks or more. The butyl aminobenzoate is released sufficiently slowly to provide just enough anesthetic action to block pain sensation traveling through the nerves in the body region while leaving intact most other nerve conduction functions (column 3, lines 11-25).

Shulman does not teach or suggest that the administration of polyethylene glycol is effective to restore nerve impulse conduction through an injured spinal cord. Rather, Shulman teaches that stable, suspensions of butyl aminobenzoate in polyethylene glycol provide "anesthetic action to block pain sensation traveling through the nerves in the body region while leaving intact most other nerve conduction functions" (column 3, lines 20-25). Appellants

submit that Shulman does not teach or suggest that the administration of polyethylene glycol is effective to treat spinal cord injuries and does not teach the administration of *an effective amount* of polyethylene glycol, *wherein the effective amount* of polyethylene glycol *is effective to restore nerve impulse conduction through said injured spinal cord.* Shulman does not teach or suggest all the limitations of the claimed methods.

This deficiency is not corrected by Edwards, which is silent as to polyethylene glycol or C1-C10 polyalkylene glycols in general. Edwards teaches "a surgically implanted spinal fixation device and method which permits improved correction of deformity and provides increased stability in the fixation of spinal fractures and other spinal deformities such as scoliosis and kyphosis" (column 1, lines 6-10). Appellants submit Shulman in view of Edwards does not teach or suggest all of the limitations of the claimed methods of treating spinal cord injuries.

Appellants further submit that Shulman in view of Edwards does not teach or suggest all of the limitations of the methods of dependent claims 30, 40, and 43. Dependent claim 30 is drawn to the claimed method of treating spinal cord injuries "wherein said method further comprises the step of contacting said injured spinal cord with a synergistic amount of 4-aminopyridine and within an effective time of contacting said spinal cord with said polyethylene glycol so as to produce a synergistic increase in restoration of nerve function and reflex behavior in said patient" and dependent claims 40 and 43 are drawn to the claimed method of treating spinal cord injuries "further comprising the step of contacting said injured spinal cord with a potassium channel blocker in the form of 4-aminopyridine in an effective amount and within an effective time of contacting said spinal cord with said polyethylene glycol." Appellants submit that neither Shulman nor Edwards provide any teachings or suggestions of 4-aminopyridine. Thus, Shulman in view of Edwards does not teach or suggest all of the limitations of the methods of claims 30, 40, and 43.

The Examiner has apparently cited Edwards solely for its teachings that "[t]he fractured spine deforms the human structure to varying extents, creating various degrees of instability and always causing pain" (column 7, lines 22-24 of Edwards), asserting that "[o]ne of ordinary skill in the art would have been motivated to employ the PEG containing composition of Shulman in the treatment of spinal cord fractures and injury. It is known that severe spinal cord injury and

fracture lead to pain" (page 10, Office Action mailed February 23, 2005). While Appellants do not deny that spinal fractures and deformities likely cause pain, Appellants submit that there is no suggestion or motivation to combine the disclosure of Shulman with that of Edwards.

Shulman is directed to the administration of compositions of butyl aminobenzoate for producing lasting pain relief in a body by injection (Abstract). The teachings found in Shulman pertaining to polyethylene glycol are very clearly directed to the use of polyethylene glycols as water soluble suspension agent for the insoluble butyl aminobenzoate (see, for example, the Abstract, col. 2, lines 4-8 and lines 42-49, col. 5, lines 43-45, and col. 6, lines 55-68). Shulman teaches that suspensions of butyl aminobenzoate in polyethylene glycol provide pain relief by providing "anesthetic action to block pain sensation traveling through the nerves in the body region while leaving intact most other nerve conduction functions (col. 3, lines 20-25).

Edwards, on the other hand, describes methods for treating spinal fractures and other spinal deformities such as scoliosis and kyphosis (col. 1, lines 6-10). Appellants submit that there is no suggestion or motivation to combine the disclosure of Shulman with that of Edwards and claims 22-30, 38-40, 43, and 44 are patentable under 35 U.S.C. §103(a).

In conclusion, Appellants submit that Shulman in view of Edwards does not teach or suggest all of the limitations of claims 22-30, 38-40, 43, and 44. Appellants submit there is no suggestion or motivation to combine the disclosure of Shulman with that of Edwards. The Examiner has failed to meet the requisite burden of establishing a *prima facie* case of obviousness under 35 U.S.C. §103(a). Accordingly, review and reversal of this rejection of the claims under 35 U.S.C. § 103 is respectfully requested.

VIII. CONCLUSION

For the foregoing reasons, Appellants respectfully request that the Board review and reverse the rejections of claims 22-30, 38-40, 43, and 44 as discussed herein, and further that the Board direct the issuance of a Notice of Allowance of claims 22-30, 38-40, 43, and 44.

Respectfully submitted,

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November 23, 2005
Date

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CLAIMS APPENDIX

Serial No.: 09/438,206

Docket No.: 290.00420101

Claims 1-44 are provided below.

1-21 (Canceled)

22. (Rejected) A method of treating a mammalian patient having suffered an injury to its spinal cord, said method comprising contacting the injured spinal cord after the injury but within a period no greater than about 24 hours after said injury with a composition comprising an effective amount of at least one C1-C10 polyalkylene glycol, wherein the effective amount of at least one C1-C10 polyalkylene glycol is effective to restore nerve impulse conduction through said injured spinal cord.

23. (Rejected) The method according to claim 22 wherein said spinal cord is severed.

24. (Rejected) The method according to claim 22 wherein said spinal cord is crushed spinal cord.

25. (Rejected) The method according to claim 22 wherein said polyalkylene glycol is selected from the group consisting of polymethylene glycol, polyethylene glycol, polypropylene glycol, polybutylene glycol, polypentylene glycol, polyhexylene glycol, polyheptylene glycol, polyoctylene glycol, polynonylene glycol, polydecylene glycol and mixtures, thereof.

26. (Rejected) The method according to claim 25 wherein said polyalkylene glycol is administered to said patient in a pharmaceutically acceptable carrier.

27. (Rejected) The method according to claim 26 wherein said polyalkylene glycol is selected

from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof.

28. (Rejected) The method according to claim 22 wherein said polyalkylene glycol is polyethylene glycol.

29. (Rejected) The method according to claim 26 wherein said polyalkylene glycol is polyethylene glycol having a molecular weight ranging from about 40 daltons to about 3500 daltons.

30. (Rejected) The method according to claim 22, wherein said polyalkylene glycol is polyethylene glycol and wherein said method further comprises the step of contacting said injured spinal cord with a synergistic amount of 4-aminopyridine and within an effective time of contacting said spinal cord with said polyethylene glycol so as to produce a synergistic increase in restoration of nerve function and reflex behavior in said patient.

31-37 (Canceled)

38. (Rejected) A method of treating a mammalian patient having suffered an injury to its spinal cord, said method comprising contacting the injured spinal cord after the injury but within a period no greater than about 24 hours after said injury with a composition comprising an effective amount of polyethylene glycol, wherein the effective amount of polyethylene glycol is effective to restore nerve impulse conduction through said injured spinal cord.

39. (Rejected) The method according to claim 38 wherein said polyethylene glycol has a molecular weight ranging from about 40 daltons to about 3500 daltons.

40. (Rejected) The method according to claim 38 further comprising the step of contacting said injured spinal cord with a potassium channel blocker in the form of 4-aminopyridine in an effective amount and within an effective time of contacting said spinal cord with said

polyethylene glycol.

41-42 (Canceled)

43. (Rejected) The method according to claim 40 wherein said polyethylene glycol has a molecular weight ranging from about 40 daltons to about 3500 daltons.

44. (Rejected) The method according to claim 22 or 38 wherein the restoration of nerve impulse conduction is evidenced by a detectable increase in conduction action potentials, observation of anatomical continuity, restoration of more than one spinal root level, or an increase in reflex behavior.

EVIDENCE APPENDIX

Serial No.: 09/438,206

Docket No.: 290.00420101

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1. *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) entered into the record by citation herein.

2. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1005 (Fed. Circ. 1997) entered into the record by citation herein.

3. Selby (Letter to the Editor, Neurosurgery 1983;12:591), entered into the record by citation within the non-final Office Action mailed February 23, 2005.

4. M.P.E.P. § 2164.08(b) (Eighth Edition), entered into the record by citation herein.

5. *Atlas Powder Co. v. E.I. du Pont de Nemors & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed Cir. 1984), entered into the record by citation herein.

6. *In re Dinh-Nguyen*, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974), entered into the record by citation herein.

7. Benzon et al. (Anesth. Analg. 66:553-59, 1987), entered into the record by citation within the non-final Office Action mailed February 23, 2005.

8. U.S. Patent No. 5,382,584 (Balasubramanian), entered into the record by citation within the non-final Office Action mailed October 29, 2003.

9. Potter et al. (Clin. Invest Med, 1996;19(4) Suppl. S80 #533), entered into the record by citation within the non-final Office Action mailed February 27, 2001.

10. M.P.E.P. § 2142 (Eighth Edition), entered into the record by citation herein.

11. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), entered into the record by citation herein.

12. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1274, 23 USPQ2d 1839, 1840 (Fed Cir. 1992), entered into the record by citation herein

13. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), entered into the record by citation within the non-final Office Action mailed February 27, 2001.

14. U.S. Patent No. 4,599,354 (Shulman), entered into the record by citation within the non-final Office Action mailed February 23, 2005.

15. U.S. Patent No. 4,369,769 (Edwards), entered into the record by citation within the non-final Office Action mailed February 23, 2005.

RELATED PROCEEDINGS APPENDIX

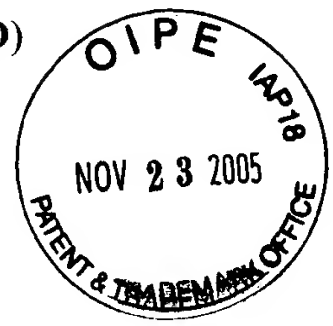
Serial No.: 09/438,206

Docket No.: 290.00420101

None

Intellectual Property Library ISSN 1526-8535

FULL TEXT OF CASES (USPQ2D)
All Other Cases



Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 Genentech Inc. v. Novo Nordisk A/S

U.S. Court of Appeals Federal Circuit
42 USPQ2d 1001

Decided March 13, 1997
No. 96-1440

Headnotes

PATENTS

1. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Specification of patent in suit would not have enabled person of ordinary skill in art at time of filing to use cleavable fusion expression to make human growth hormone without undue experimentation, since specification merely describes three or four applications for which cleavable fusion expression is generally well-suited, and names enzyme that might be used as cleavage agent as well as sites at which it cleaves, and thus does not describe specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work, and since evidence does not support patentee's contention that disclosure of DNA encoding hGH, combined with prior art cleavable fusion expression techniques applied to non-human proteins, would enable practice of claimed method.

2. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Rule that specification need not disclose what is well known in art means only that omission of minor details does not cause specification to fail to meet enablement requirement, and is not substitute for basic enabling disclosure; if there is no disclosure of any starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art.

3. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Specification that states problem of obtaining human growth hormone from precursor containing added protein material does not enable claim for method of producing hGH using cleavable fusion expression, since specification discloses method in which problem is solved by obtaining hGH unaccompanied by leader sequence or other extraneous proteins, but does not provide specific enabling disclosure for obtaining hGH by cleaving hGH-containing protein as recited in claim.

4. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Fact that no one had been able to produce any human protein via cleavable fusion expression as of application date of patent in suit undermines patentee's contention that specification's disclosure of DNA sequence encoding human growth hormone and single example enzyme and its cleavage site, without more, would have enabled one skilled in art to have used claimed cleavable fusion expression method to make hGH without undue experimentation; moreover, if disclosure of useful conjugate protein and method for its cleavage were clearly within skill of art, as patentee asserts, it would have been expressly disclosed in specification, and in customary detail.

Particular patents -- Chemical -- Human growth hormone

5,424,199, Goeddel and Heyneker, human growth hormone, invalid for lack of enablement.

Case History and Disposition:

Page 1002

Appeal from the U.S. District Court for the Southern District of New York, Motley, J.

Action by Genentech Inc. against Novo Nordisk A/S, Novo Nordisk of North America Inc., and Novo Nordisk Pharmaceuticals Inc. for patent infringement. From grant of plaintiff's motion for preliminary injunction, defendants appeal. Injunction vacated; patent held invalid as matter of law for failure of specification to enable practice of claimed method.

Prior decision: 37 USPQ2d 1773 .

Attorneys:

Leora Ben-Ami, John E. Kidd, Nicholas L. Coch, Joseph Ferraro, Philip E. Roux, and Gerard P. Norton, of Rogers & Wells, New York, N.Y.; Ryan Trainer, of Rogers & Wells, Washington, D.C., for plaintiff-appellee.

Albert L. Jacobs Jr., Jesse D. Reingold, Gerard F. Diebner, Daniel A. Ladow, Brad S. Needleman, and Andrew T. Solomon, of Graham & James, New York; John C. Vassil, Kurt E. Richter, and Kenneth H. Sonnenfeld, of Morgan & Finnegan, New York, for defendants-appellants.

Judge:

Before Archer chief judge, and Lourie and Bryson, circuit judges.

Opinion Text

Opinion By:

Lourie, J.

Novo Nordisk A/S, Novo Nordisk of North America, Inc., and Novo Nordisk Pharmaceuticals, Inc. (collectively "Novo") appeal from the order of the United States District Court for the Southern District of New York, issuing a preliminary injunction in favor of Genentech, Inc., enjoining Novo from importing, marketing, using, selling, offering for sale or distributing its Norditropin(Registered)-brand recombinant human growth hormone (hGH) product. *Genentech, Inc. v. Novo Nordisk A/S* , 935 F. Supp. 260 (S.D.N.Y. 1996). Because the district court's conclusion that Genentech had demonstrated a likelihood of success on the merits was based on an error of law and because its remaining findings were premised on this error, we vacate the injunction.

BACKGROUND

This consolidated patent infringement action was first brought in the United States District Court for the Southern District of New York on November 30, 1994. On May 12, 1995, Genentech moved for a preliminary injunction under U.S. Patent 4,601,980 to prevent Novo from importing, marketing, using, selling, offering for sale or distributing in the United States its Norditropin(Registered)-brand recombinant hGH product. The district court granted Genentech's motion and issued an injunction. *Novo Nordisk of North Am., Inc. v. Genentech, Inc.* , No. 94 Civ. 8634 (CBM), 1995 U.S. Dist. LEXIS 12588, 1995 WL 512171 (S.D.N.Y. Aug. 28, 1995).

On appeal this court vacated the injunction. *Novo Nordisk of North Am., Inc. v. Genentech, Inc.* , 77 F.3d 1364, 37 USPQ2d 1773 (Fed. Cir. 1996). We held that the district court clearly erred in finding that Genentech established a likelihood of proving infringement of the '980 patent because that finding was based on an improper construction of claim 2 of the patent. Based upon the specification and prosecution history, we concluded that because the claim used the phrase "human growth hormone unaccompanied by . . . other extraneous protein," it was limited to processes for directly expressing either hGH or met-hGH. *Id.* at 1371, 37 USPQ2d at 1779. Because the parties agreed that Novo did not use direct expression to produce these proteins, we concluded that Novo did not infringe the patent. *Id.*

Upon returning to the district court, Genentech asserted its newly issued U.S. Patent 5,424,199. The '199 patent has the same specification as the '980 patent and contains a single claim directed to:

[a] method of producing a protein consisting essentially of amino acids 1-191 of human growth hormone comprising:

(a) expressing in a transformant bacterium, DNA coding for a human growth hormone conjugate protein, which conjugate protein consists essentially of amino acids 1-191 of human growth hormone as set forth in combined Figs. 1 and 3 unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto and an additional amino acid sequence which is specifically cleavable by enzymatic action, and

(b) cleaving extracellularly said conjugate protein by enzymatic action to produce said protein consisting essentially of amino acids 1-191 of human growth hormone.

This claim differs from the claim adjudicated in the prior case in reciting that the encoded protein has an additional amino acid sequence and includes the step of cleaving this conjugate protein. This process of expressing a DNA encoding a conjugate protein and using an enzyme to cleave off an undesired portion of that protein is generally known as cleavable fusion expression. The parties agree that Novo uses cleavable fusion expression to produce hGH. *Id.*

On June 27, 1996, after conducting a twelve-day evidentiary hearing, the district court again issued a preliminary injunction, this time based upon the '199 patent, enjoining Novo from importing, marketing, using, selling, offering for sale, or distributing in the United States its Norditropin(Registered)-brand recombinant hGH product. *Genentech v. Novo Nordisk A/S* , 935 F. Supp. 260 (S.D.N.Y. 1996). The district court based its

decision upon, *inter alia* , a finding that Genentech would likely overcome Novo's defense that the '199 patent was invalid for lack of an enabling disclosure under 35 U.S.C. Section 112, Para. 1 (1994).
Novo appeals to this court, challenging the grant of the preliminary injunction. 1 We have jurisdiction pursuant to 28 U.S.C. Section 1292 (c) (1994).

DISCUSSION

The grant or denial of a preliminary injunction pursuant to 35 U.S.C. Section 283 is within the discretion of a district court. *We Care, Inc. v. Ultra-Mark Int'l Corp.* , 930 F.2d 1567, 1570, 18 USPQ2d 1562, 1564 (Fed. Cir. 1991). Accordingly, a trial court's decision granting a preliminary injunction will be overturned on appeal only upon a showing that the court abused its discretion. *Joy Techs., Inc. v. Flakt, Inc.* , 6 F.3d 770, 772, 28 USPQ2d 1378, 1380 (Fed. Cir. 1993). Such an abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings. *Id.*
As the moving party, Genentech had to establish its right to a preliminary injunction in light of four factors: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of the hardships; and (4) the impact of the injunction on the public interest. *Nutrition 21 v. United States* , 930 F.2d 867, 869, 18 USPQ2d 1347, 1348-49 (Fed. Cir. 1991); *Hybritech Inc. v. Abbott Lab.* , 849 F.2d 1446, 1451, 7 USPQ2d 1191, 1195 (Fed. Cir. 1988).
A. *Likelihood of Success on the Merits*
In order to demonstrate that it has a likelihood of success, Genentech must show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove that Novo infringes the '199 patent and (2) its infringement claim will likely withstand Novo's challenges to the validity and enforceability of the '199 patent. *See New England Braiding Co. v. A.W. Chesterton Co.* , 970 F.2d 878, 882-83, 23 USPQ2d 1622, 1625-26 (Fed. Cir. 1992). 2 In other words, if Novo raises a "substantial question" concerning validity, enforceability, or infringement (*i.e.* , asserts a defense that Genentech cannot show "lacks substantial merit") the preliminary injunction should not issue. *Id.* More specifically, with regard to Novo's validity defenses, the question on appeal is whether there is substantial merit to Novo's assertion that the '199 patent claim fails to meet the requirements of 35 U.S.C. Section 112, Para. 1 (1994).
Novo argues that the district court's findings regarding validity under Section 112, Para. 1, are clearly erroneous because it presented clear and convincing evidence that the patent specification would not have enabled a person of ordinary skill in the art to practice the claimed invention without undue experimentation. Novo also argues that the specification fails to contain a written description of the claimed invention. Regarding enablement, Novo argues that the patent is invalid because it does not contain sufficient detail concerning the practice of the claimed method. Novo argues that the mere generic statement of the possibility of cleavable fusion

expression, along with the DNA sequence encoding hGH, a single enzyme (trypsin) for

cleaving undisclosed conjugate proteins, and a statement of that enzyme's cleavage sites as being potential amino acid extensions conjugated to hGH is not an enabling disclosure commensurate in scope with the claim. Genentech responds that all of the district court's factual findings regarding enablement are supported by the record. More specifically, Genentech argues that those skilled in the art of recombinant protein expression and purification at the time of filing, July 5, 1979, would have been able to use cleavable fusion expression to produce hGH without undue experimentation by using the teachings of the specification along with methods and tools well known in the art. We conclude that Novo has raised more than a substantial question concerning the validity of the '199 patent. In fact, it has shown that the patent is invalid.

Section Section 112, Para. 1, provides, in relevant part that:

[t]he specification shall contain a written description of the invention, and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

" [T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *In re Wright* , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.* , 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* , 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (" [T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based upon several underlying factual inquiries. *See In re Wands* , 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988).

[1] The question before us is whether the specification would have enabled a person having ordinary skill in the art at the time of filing to use cleavable fusion expression to make hGH without undue experimentation. There is no dispute that the portion of the specification chiefly relied upon by Genentech and by the district court, column 7, lines 29-59, does not describe in any detail whatsoever how to make hGH using cleavable fusion expression. For example, no reaction conditions for the steps needed to produce hGH are provided; no description of any specific cleavable conjugate protein appears. The relevant portion of the specification merely describes three (or perhaps four) applications for which cleavable fusion expression is *generally* well-suited and then names an enzyme that might be used as a cleavage agent (trypsin), along with sites at which it cleaves ("arg-arg or lys-lys, etc."). 3 Thus, the specification does not describe a specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work.

Notwithstanding this limited disclosure, Genentech argues (and the district court found) that those of ordinary skill in the art would have been able to practice the claimed invention without undue experimentation. Essentially, Genentech's argument is that the knowledge of one skilled in the art was sufficient to provide all of the missing information and, more specifically, that the disclosure of a DNA encoding hGH, when combined with prior art cleavable fusion expression techniques applied to non-human proteins, would enable the practice of the claimed method. In support of this argument,

Genentech points to the testimony of Dr. Ravetch, who testified as to the knowledge of one skilled in the art, to the extensive description of enzymes in the reference textbook *Methods in Enzymology* , and to the specification's explicit reference to British Patent 2008123-A, which more fully details the potential use of trypsin in cleavable fusion expression.
In response to these arguments, Novo asserts that at the time of filing, trypsin and other like enzymes were used only to digest proteins, not to specifically and precisely cleave conjugate proteins to yield intact, useful proteins, and that the British patent explicitly indicates that trypsin would not be useful for the cleavable fusion expression of arginine-containing proteins such as hGH. Novo further argues that neither the specification nor the references cited by Genentech suggest a single amino acid sequence, out of the virtually infinite range of possibilities,

that would yield hGH in a useful form when cleaved from the conjugate protein.
We agree with Novo. Genentech's arguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See* *Brenner v. Manson* , 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in this specification with respect to the cleavable fusion expression of hGH.
[2] It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See* , *e.g.* , *Hybritech Inc. v. Monoclonal Antibodies, Inc.* , 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.
[3] The specification indicates that it purports to solve a problem. That problem is summarized at column 3, line 65, through column 4, line 8:
[A] need has existed for new methods of producing hGH and other polypeptide products in quantity and that need has been particularly acute in the case of polypeptides too large to admit to organic synthesis or, for that matter, microbial expression from entirely

synthetic genes. Expression of mammalian hormones from mRNA transcripts . . . has permitted only microbial production of bio-inactive conjugates from which the desired hormone could not practically be cleaved.

The problem thus was the difficulty of obtaining hGH from a precursor containing added protein material. This problem was solved by the description of a method of obtaining hGH unaccompanied by a leader sequence or other extraneous proteins, as claimed in the '980 patent. However, the specification for the '199 patent, which is the same as the specification for the '980 patent, does not provide a specific enabling disclosure concerning what the new claim recites, *viz.* , obtaining hGH by cleaving an hGH-containing conjugate protein. That was the problem avoided by the invention claimed in the '980 patent. The present specification contains no more disclosure than the '980 specification, but this patent now purports to claim the unresolved problem that the '980 patent overcame. Genentech is attempting to bootstrap a vague statement of a problem into an enabling disclosure sufficient to dominate someone else's solution of the problem. This it cannot do.

Genentech's arguments in favor of enablement are unavailing. While Genentech's witness, Dr. Ravetch, did state that it would have been possible for a skilled artisan to create a DNA sequence coding for arg- arg-hGH or lys-lys-hGH, he did not discuss the experimentation needed for the creation of DNA coding for more extensive sequences, such as those that have proved necessary to the production of hGH via cleavable fusion expression. Likewise, the description of a wide range of enzymes in *Methods in Enzymology* , by itself, does not render routine the determination of an enzyme-conjugate protein combination. Rather, as Novo argues and the record reflects, various combinations of conjugate protein sequences, cleaving enzymes, and reaction conditions needed to be studied to establish a process for producing hGH in useful form. Finally, the British patent cited in the specification actually works against Genentech's position by explicitly teaching that trypsin would not work well to produce hGH. The specification does not even acknowledge any of the known difficulties associated with using trypsin on an hGH conjugate protein. This specification is so lacking with respect to the limitation of paragraph (b) of claim 1 that providing testimony regarding the skill in the art has been an exercise in futility.

[4] The limited testimony regarding the knowledge of one skilled in the art offered by

Genentech at the preliminary injunction hearing, and relied upon by the district court, is further undermined by the fact that no one had been able to produce *any* human protein via cleavable fusion expression as of the application date. If, as Genentech argues, one skilled in the art, armed only with what the patent specification discloses (a DNA sequence encoding a human protein, in this case, hGH, and a single example of an enzyme and its cleavage site), could have used cleavable fusion expression to make a human protein without undue experimentation, it is remarkable that this method was not used to make any human protein for nearly a year, *see* Shine *et al.* , 285 Nature 456 (June 1980), or to make hGH for five years. *See* Belagaje *et al.* , 3 DNA 120 (1984). Certainly, DNAs encoding desirable human proteins were known at the time of filing (*e.g.* , insulin, described in the British patent), and a great many researchers

were attempting to produce human proteins using recombinant DNA technology. This failure of skilled scientists, who were supplied with the teachings that Genentech asserts were sufficient and who were clearly motivated to produce human proteins, indicates that producing hGH via cleavable fusion expression was not then within the skill of the art. The contrary testimony offered by Genentech's witnesses, who hypothesized about the skill of the art more than fifteen years earlier, does not demonstrate the incorrectness of Novo's arguments. *See In re Buchner* , 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ("[A]n expert's opinion on the ultimate legal issue [of enablement] must be supported by something more than a conclusory statement.").

Moreover, it stands to reason that if the disclosure of a useful conjugate protein and the method for its cleavage were so clearly within the skill of the art, it would have been expressly disclosed in the specification, and in the usual detail. Patent draftsmen are not loath to provide actual or constructive examples, with details, concerning how to make what they wish to claim. In addition, as indicated above, the specification of this patent was clearly drafted to claim the invention of obtaining hGH *unaccompanied by* extraneous protein, the cleavage of which was identified by the specification as a problem in this field. Genentech's inventors knew how to enable that which they had invented. These facts underline the inadequacy of the specification in enabling that which it provided only a means to avoid.

The record does not support the district court's implicit finding that the disclosure of trypsin and its cleavage site enables the production of any conjugate protein from which hGH can practically be cleaved and thus produced in useful form; the record indicates that determination of these features required further undue experimentation. None of the expert testimony relied upon by Genentech or by the district court suggests otherwise. 4

Where, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching. Genentech has not shown that the '199 patent provides that teaching.

Under the circumstances, we are compelled to conclude that the district court made an error of law in ruling that Genentech showed a likelihood of success on enablement. *See In re Epstein* , 32 F.3d 1559, 1568, 31 USPQ2d 1817, 1823 (Fed. Cir. 1994) ("[E]nablement is a question of law . . . which may involve subsidiary questions of fact.").

Furthermore, since we are able to review the record and to read the specification, there is no reason why we should limit our decision here to reversing the grant of the preliminary injunction. Rather, because the parties agreed at oral argument that the enablement issue had been thoroughly ventilated by the extensive arguments before the district court and that court's extensive analysis, 5 we deem it appropriate to rule on the

merits of Novo's defense of invalidity. *See* 28 U.S.C. Section 2106 (1994) ("The Supreme Court or any other court of appellate jurisdiction may . . . direct the entry of such appropriate judgment, decree, or order, or require such further proceedings to be had as may be just under the circumstances."); *Chicago Observer, Inc. v. City of Chicago* , 929 F.2d 325, 329 (7th Cir. 1991) (reversing preliminary injunction and instructing district court to enter judgment in favor of defendant because the plaintiff

"has not suggested that it holds more evidence it could offer at trial and we cannot imagine what additional evidence could aid its cause. Litigation is costly not only for the litigants but also for parties in other cases waiting in the queue for judicial attention. Once it becomes clear that additional proceedings are pointless, the court should bring the case to a close."). We therefore hold that claim 1 and hence the '199 patent are invalid as a matter of law for failure of the specification to enable the practice of the claimed method.

Novo has also argued that the '199 patent is invalid for lack of a written description of the claimed invention and that it is not infringed by Novo. Given our decision on the enablement question, we need not reach these issues.

B. *Other Factors*

Novo also challenges the district court's findings that irreparable harm, the equities, and the public interest favored Genentech. In view of our conclusion concerning the invalidity of the '199 patent, we need not consider these other findings.

CONCLUSION

The court abused its discretion by granting the preliminary injunction based upon an error of law. The district court's error was in finding that Genentech had shown a likelihood of success on the merits since the '199 patent is invalid for failure of the specification to meet the enablement requirement of Section 112, Para. 1. Accordingly, we vacate the injunction and instruct the district court to dismiss Genentech's claim for infringement of the '199 patent on the ground that the patent is invalid. *VACATED* .

Footnotes

Footnote 1. On July 3, Novo moved for an emergency stay of the injunction pending disposition of this appeal. On August 1, we denied Novo's motion and reinstated the injunction. However, after having heard oral argument in this case, we reconsidered the motion and reinstated the stay of the injunction.

Footnote 2. A patent is presumed valid, 35 U.S.C. Section 282 (1994), and a party challenging validity must prove invalidity by clear and convincing evidence. "However, the presumption does not relieve a patentee who moves for preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity." *New England Braiding* , 970 F.2d at 882, 23 USPQ2d at 1625 (citing *Nutrition 21* , 930 F.2d at 869, 18 USPQ2d at 1349).

Footnote 3. At column 7, lines 52-58, the specification states: "At least in the latter three applications [of the four applications that are disclosed], the synthetic adaptor molecular [sic] employed to complete the coding sequence of the mRNA transcript can additionally incorporate codons for amino acid sequences specifically cleavable, as by enzymatic action. For example, trypsin will cleave specifically at arg-arg or lys-lys, etc."

Footnote 4. Novo's witness, Dr. Villa-Komaroff, merely stated on cross-examination that, assuming arg- arg-hGH was initially produced and successfully extracted from the

transformed cell, that " [u]nder the best condition, approximately five percent of the time there will be in the [post-digestion] mix [hGH]." This statement, characterized by Genentech as an admission, was made in the limited context of partial trypsin digests of isolated arg-arg-hGH, but none of the necessary experimentation is described in the specification, which is where it should be if it is to contribute to an enabling disclosure. Footnote 5. Genentech stated that it would introduce new evidence at a full trial only in response to new arguments and new defenses raised by Novo. Novo revealed that it had no intention of raising any new arguments or defenses, stating that the "full and complete record" on appeal gave this court "the benefit of everything it really needs" to reach ultimate issues of validity. Thus, considerations that would normally dictate that we limit our decision to reversing the grant of the preliminary injunction are not present. *See University of Texas v. Camenisch* , 451 U.S. 390, 395 (1981) (stating that it is generally inappropriate to render a final judgment on the merits at the preliminary injunction stage because "a preliminary injunction is customarily granted on the basis of procedures that are less formal and *evidence that is less complete than in a trial on the merits* .") (citations omitted) (emphasis added).

- End of Case -

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General Foods Corp. v. Studiengesellschaft Kohle mbH (CA FC) 23 USPQ2d 1839 General Foods Corp. v. Studiengesellschaft Kohle mbH

U.S. Court of Appeals Federal Circuit
23 USPQ2d 1839

Decided August 11, 1992
No. 91-1418

Headnotes

PATENTS

1. Patent construction -- Claims -- In general (§ 125.1301)

Each patent claim is entity which must be considered as whole; thus, it cannot be said that part of claim is "claimed" subject matter.

2. Patentability/Validity -- Anticipation -- Double patenting (§ 115.0708)

Law of double patenting is concerned only with what patents claim, and thus involves inquiry into what, if anything, has been claimed twice.

3. Patentability/Validity -- Anticipation -- Double patenting (§ 115.0708)

Determining factor in deciding whether or not double patenting exists is existence vel

non of patentable difference between two sets of claims; fact that it may be desirable to use both inventions in same commercial process does not itself result in any recognized form of double patenting.

4. Patentability/Validity -- Anticipation -- Double patenting (§ 115.0708)

Basic concept of double patenting is that same invention cannot be patented more than once, but double patenting law is in fact more inclusive, with double patenting principles extending to cover merely obvious variants of what has been patented; claims are determinants used to determine exactly what has been patented.

5. Patentability/Validity -- Anticipation -- Double patenting (§ 115.0708)

Disclosure of patent cited in support of double patenting rejection cannot be used as though it were prior art, even if disclosure is found in claims.

Particular patents -- Chemical -- Coffee decaffeination

4,260,639, Zosel, process for the decaffeination of coffee, judgment of invalidity on grounds of double patenting reversed.

Case History and Disposition:

Appeal from the U.S. District Court for the Southern District of New York, Goettel, J; 20 USPQ2d 1673.

Action by General Foods Corp. against Studiengesellschaft Kohle mbH for declaration of patent invalidity and non-infringement. From federal district court decision holding claims invalid, defendant appeals. Reversed and remanded.

Attorneys:

Paul H. Heller, of Kenyon & Kenyon (Richard L. DeLucia, James Galbraith, and Richard S. Gresalfi, with him on brief), New York, N.Y., for plaintiff-appellee.

Arnold Sprung, of Sprung, Horn, Kramer & Woods (Nathaniel D. Kramer, with him on brief), Tarrytown, N.Y., for defendant-appellant.

Judge:

Before Skelton, senior circuit judge, and Rich and Clevenger, circuit judges.

Opinion Text

Opinion By:

Rich, J.

Studiengesellschaft Kohle mbH (SGK), as trustee for real-party-in-interest Max Planck Institute for Coal Research, appeals from the June 12, 1991 judgment of the United States District Court for the Southern District of New York, Civil Action No. 88-8343, declaring invalid claims 1 and 4 of SGK's U. S. Patent No. 4,260,639 ('639 patent), titled "Process for the Decaffeination of Coffee," on the sole ground of "double patenting," in view of SGK's earlier-issued U.S. Patent No. 3,806,619 ('619 patent), titled "Process for Recovering Caffeine." Because there is no double patenting, we reverse.

BACKGROUND

This declaratory judgment suit is between a licensor and licensee over patents relating to decaffeinated coffee. Plaintiff, General Foods Corporation (GF), owns Maxwell House Coffee Company which manufactures decaffeinated coffee at its AMCO plant in Houston, Texas, for sale under brands such as Sanka, Maxim, Brim, Yuban, and Maxwell House. GF also owns Kaffee HAG, a processor and research com

pany in Bremen, Germany, which is said to have been the first producer of decaffeinated coffee.

SGK developed in Europe inventions relating to decaffeination and owned five United States patents involved in this lawsuit. Learning about SGK's developments, GF entered into an exclusive license agreement with SGK effective February 1, 1978, which has now become a nonexclusive license, on which it paid royalties to SGK through 1990, since then paying further royalties under protest. The license agreement provided for advance payments totalling $1,800,000 during the first year. Royalties were to range from 1.75% of net decaffeinated coffee sales up to 40,000,000 pounds down to 1.25% of net sales over 120,000,000 pounds.

GF brought this suit for a declaration of non-infringement, invalidity, and unenforceability as to all five patents. However, the District Court found that although all five SGK patents were licensed, SGK now asserts that only claims 1 and 4 of the '639 patent would be infringed by GF's operation at the AMCO plant and that the other four patents are no longer in suit. Although GF asserted numerous defenses against claims 1 and 4, including invalidity for "obviousness-type double patenting," non-infringement, obviousness under 35 USC 103, non-enablement under 35 USC 112, and unenforceability due to inequitable conduct before the Patent and Trademark Office

(PTO), the District Court issued an Order of Trial on April 5, 1991, on GF's motion, to "bifurcate the issue of double patenting." The order further stated, "If the decision does not dispose of the action, trial will then immediately continue on the remaining issues."

The District Court held a separate trial on the single issue of double patenting. A judgment was entered holding claims 1 and 4 of the '639 patent invalid, thus terminating GF's declaratory judgment suit seeking invalidity of the only patent it was alleged to be infringing and putting an end to its obligation to pay SGK royalties under its contract.

This appeal followed and, as above stated, there is only one issue for us to decide -- is there double patenting. We shall first discuss the facts regarding the two patents involved and then the law of double patenting as it applies to those facts.

Patent Claims

Preliminarily, in order to better focus on the crucial aspects of the patents under discussion, we make the following elementary observations about patent claims. The patent document which grants the patentee a right to exclude others and hence bestows on the owner the power to license, consists of two primary parts: (1) a written description of the invention, which may and here does include drawings, called the "specification," enabling those skilled in the art to practice the invention, and (2) claims which define or delimit the scope of the legal protection which the government grant gives the patent owner, the patent "monopoly." As stated by Judge Lane, who served on both of our predecessor courts, in *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970), "A claim is a group of words defining only the *boundary* of the patent monopoly." (Emphasis ours.) The Supreme Court has likened patent claims to the description of real property in a deed "which sets the bounds to the grant which it contains. It is to the claims of every patent, therefore, that we must turn when we are seeking to *determine what the invention is, the exclusive use of which is given to the inventor by the grant* provided for in the statute, -- 'He can claim nothing beyond them.' " *Motion Picture Patents Co. v. Universal Film Mfg. Co.,* 243 U.S. 502, 510 (1917) (emphasis ours).

[1] That being the essential nature of patent claims, it follows that each claim is an *entity* which must be considered *as a whole.* It cannot be said -- though it often is, incorrectly, by the uninitiated -- that a part of a claim is "claimed" subject matter. For example, a claim to a process comprising the step A followed by step B followed by step C defines, as a matter of law, only the A-B-C process and one cannot properly speak of any single step as being "claimed", for it is not; all that is claimed is the process consisting of the *combination* of all three steps. Such a claim, therefore, creates no patent right or monopoly in step A, no right to prevent others from using step A apart from the combination of steps A-B-C. Step A is not "patented."

Another way of stating the legal truism is that patent claims, being definitions which must be read *as a whole,* do not "claim" or cover or protect all that their words may *disclose.* Even though the claim to the A-B-C combination of steps contains a detailed description of step A, that does not give the patentee any patent right in step A and it is legally incorrect to say that step A is "patented."

[2] These legal rules about construing claims are repeated here because the law of double patenting is concerned *only* with what patents *claim.* "Double patenting," therefore, involves an inquiry into what, if anything, has been claimed twice.

The Patent in Suit and its Claimed Invention

Coffee beans contain a small percentage of caffeine which must be removed to produce decaffeinated coffee. The inventor, Kurt Zosel, working in Germany for SGK, discovered that moist (i.e., containing water) "supercritical" carbon dioxide, that is, carbon dioxide above its critical temperature and critical pressure, was an excellent solvent for taking the caffeine out of coffee beans. That was the basic invention. The parties and the trial court have referred to the patent on this invention as "the decaffeination patent."

A U.S. application for patent on this invention was filed January 28, 1971, serial No. 110,428. This application was prosecuted to the point where all pending claims were allowed following the usual debate with the examiner over unobviousness in view of prior art references. The official Notice of Allowance was mailed by the PTO March 8, 1973. Payment of the base issue fee was due within three months, June 8, 1973.

Upon examining the 13 allowed claims prior to issue, Zosel and/or his attorneys realized that all claims were limited to *raw* coffee beans and it was concluded that the application disclosure would support broader claims not limited to raw coffee, but broad enough to include roasted coffee; i.e., claims simply calling for "coffee." It was decided, therefore, to file a continuation-in-part application (a CIP) with such broader claims. This was done within the time limit allowed by PTO rules and application Serial No. 364,190 was filed on May 25, 1973. Original application Serial No. 110,428, according to the usual practice, was allowed to go abandoned.

The try for broader claims did not succeed in a prosecution that was hard fought and went all the way to the PTO Board of Patent Appeals and Interferences (Board). Zosel and his assignee SGK ended up with a Board decision on July 12, 1979, that allowed claims to no more than had originally been allowed, claims to the new process as applied to raw coffee beans. The Board held the disclosure in Zosel's original application did not support claims naming "coffee" generally, wherefore he was entitled only to the filing date of the CIP, to which he had added supporting disclosure. Given that filing date, there was new prior art which barred claims not restricted to raw coffee. The Board said:

> We affirm the rejection of claims 1-14 [the new broad coffee claims] under 35 USC 102(d) as anticipated by the British patent. Contrary to appellant's assertion, the decaffeination of coffee in general, i.e. from both its raw and roasted state, by the claimed expedient is not implicit in the disclosure of the parent application.

We are not concerned on this appeal with this aspect of the Board's decision. It simply concluded Zosel's effort to get broad "coffee" claims.

The more interesting aspect of the Board's decision relates to the double patenting issue now before us. During the CIP prosecution, the Examiner had made obviousness-type double patenting rejections based on the claims of Zosel's U.S. Patent No. 3,806,619, issued April 23, 1974, the same '619 patent relied on by the District Court in support of the double patenting decision here under review. The double patenting issue was extensively debated between the Examiner and applicant's attorney and went to the

Board on appeal from the Examiner's final rejection. The Board reversed the Examiner's rejections for obviousness-type double patenting. The Board concluded (emphasis ours):

In re Borah, 53 CCPA 800, 354 F.2d 1009, 148 USPQ 213 [(CCPA 1966)], supports appellant's position that the test for double patenting is whether or not the subject matter of the patent claims is obvious from the subject matter of the claims at issue. Clearly, here, steps (b) through (j) of the ['619] patent claims are not suggested by nor obvious from the claims at bar, the patent claims being a *separate and distinct* improvement invention thereover, and, consequently, *no* double patenting rejection is seen to be proper.

Thereafter, Zosel cancelled the rejected claims, received a Notice of Allowance, and the '639 patent in suit was issued on April 7, 1981.

Claims 1 and 4 of the '639 patent, held invalid in this suit for double patenting in view of the '619 patent, contrary to the unanimous decision of the Board on the identical issue, read as follows:

1. A process for the decaffeination of raw coffee which comprises contacting the raw coffee with water-moist carbon dioxide above its critical temperature and critical pressure to effect removal of caffeine therefrom and recovering a substantially decaffeinated coffee, the amount of water in the carbon dioxide being sufficient to effectuate said removal of the caffeine from the coffee.

4. A process as claimed in claim 1, in which the contact with the moist carbon dioxide is effected for a period of from 5 to 30 hours.

It will be observed that this process consists of two steps: (1) a caffeine removal step and (2) a decaffeinated-coffee recovery step. The claim 4 time limitation addition to claim 1 is of no significance to the decision of the issue here.

The Invention of Claim 1 of the '619 Patent Relied on Below to Show Double Patenting

Zosel, more than a year after he had filed his foreign application to patent his decaffeination process, on which his U.S. parent and CIP applications were based, made a further invention which the parties have characterized as an "improvement" on the original process. It is, however, a separate invention, unrelated to the decaffeination invention defined in claims 1 and 4. Its purpose was to effect an efficient removal *from the supercritical carbon dioxide solvent,* used to extract caffeine from the raw coffee beans, *of the caffeine* removed so as *to obtain caffeine* of better than 95% purity. The shorter version of the general description of this recovery process in the '619 patent is as follows: 1

[The process for recovering caffeine] which comprises removing the caffein from the caffein-loaded carbon dioxide by repeated treatment with water and recovering the caffein and the water from the resultant dilute aqueous caffein solution by recycling a stream of air or nitrogen under a superatmospheric pressure of about 1 to 5 atmospheres through the heated caffein solution and a heat exchanger, separating the caffein and the

condensed water and recycling after admixture of cold caffein solution the gas through the heat exchanger in countercurrent flow relation and meeting the heat requirement by supplying heat to the hot caffein solution.

The patent specification then proceeds with a detailed description of the recovery process in conjunction with a drawing of the processing apparatus employed.

What has caused much of the argument and most of the confusion in this case is the brief reference in the '619 patent to the '639 patent decaffeination process as the source of the caffeine in the "caffein-loaded carbon dioxide" which is the input to the recovery process. The totality of that reference in the '619 patent is in the opening paragraphs of the specification:

Austrian Pat. No. 290,962 and U.S. [CIP] application Ser. No. 364,190, filed May 25, 1973 disclose a process for decaffeinating green coffee, wherein moist carbon dioxide is recycled through a bed of green coffee and a bed of activated charcoal. The moist carbon dioxide passes through the green coffee bed in supercritical state and through the bed of activated charcoal at a lower temperature in liquified state. The moist carbon dioxide in supercritical state is loaded thereby with the caffein of the green coffee and the caffein is absorbed on the activated charcoal.

The recovery of the caffein from the activated charcoal is not described in the patent mentioned above.

The parties and trial court have appropriately referred to the '619 patent as "the caffeine recovery patent."

It should be amply clear by now that the decaffeination *invention* and the caffeine recovery *invention* are separate and distinct inventions, directed to different objectives, and *patentably distinguishable* one from the other. Neither is statutory "prior art" to the other because the patent applications were copending and, further, because there can be no "prior invention *by another* " (cf. 35 USC 102(g)) because both are the inventions of Zosel.

Claim 1 of the '619 patent, on the basis of which the District Court found double patenting, reads:

1. A process for obtaining caffein from green coffee which comprises:

a. contacting moist carbon dioxide in supercritical state with the coffee in a caffein absorption zone for absorption of caffein by the moist carbon dioxide,

b. withdrawing the moist carbon dioxide containing absorbed caffein from the absorption zone and contacting it with water for extraction of caffein from the moist carbon dioxide in an extraction zone for formation of an aqueous solution of caffein,

c. recirculating the moist carbon dioxide between the absorption zone and the contacting zone.

d. withdrawing aqueous solution of carbon dioxide from the extracting zone and introducing it into an evaporating zone, passing a stream of air or nitrogen through the aqueous solution in the evaporating zone for evaporation of water from solution and concentration of caffein in the aqueous solution, and withdrawing a concentrated aqueous solution from the evaporating zone,

e. withdrawing the air or nitrogen laden with water vapor from the evaporating zone and cooling it for condensation of water and separating the water from the air or nitrogen in a separating zone,

f. recirculating the air or nitrogen between the evaporating zone and the separating zone,

g. admixing aqueous solution of carbon dioxide from the extraction zone with the air or nitrogen conveyed from the separating zone to the evaporating zone.

h. passing the air or nitrogen laden with water vapor and the admixture formed in step (g) in indirect heat exchange relation between the evaporating zone and the separating zone, for cooling of the air or nitrogen laden with water vapor for the condensation of step (e) and heating said admixture for heating the aqueous solution for the evaporation, and

[sic -- no step i.]

j. supplying additional heat to the aqueous solution for the evaporation.

That this claim 1 of the '619 patent is the *sole* basis of the ultimate double patenting holding of the trial court is shown in its Conclusion of Law 24, which reads:

24. For all the foregoing reasons, we find [sic, hold] that claim 1 of the decaffeination patent ['639] is obvious from claim 1(a) of the caffeine recovery patent ['619]. Consequently, plaintiff is entitled to a judgment declaring claim 1 of the decaffeination patent invalid on the ground of obviousness-type double patenting.

ANALYSIS

Double patenting is altogether a matter of what is claimed. Claim interpretation is a question of law which we review de novo. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 228 USPQ 90 (Fed. Cir. 1985). As we construe the claims here involved, claims 1 and 4 of the patent in suit, '639, define a process of decaffeinating raw coffee with supercritical water-moist carbon dioxide and recovering the decaffeinated coffee. They say nothing about what happens to the caffeine. Claim 1 of the '619 patent, relied on to show double patenting, defines a *9- step process* of "obtaining caffein from green coffee." Anything less than a process with all 9 steps is not what is claimed, and is, therefore, not patented. Claims must be read as a whole in analyzing a claim of double patenting. *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 940, 220 USPQ 481, 487 (Fed. Cir. 1983) ("we wish to clarify that double patenting is determined by analysis of the claims as a whole.") These two inventions, decaffeination of coffee and recovery of caffeine, are separate, *patentably distinct* inventions between which there cannot be double patenting. Clearly the two patents do not claim the *same* invention, and this is not argued. Under an obviousness-type double patenting analysis, neither *claimed* process is a mere obvious variation of the other. No other kind of "double patenting" is recognized, so there is no double patenting. That concludes the case so far as this appeal is concerned. A discussion of the law which supports our conclusion follows.

No Double Patenting Between Patentably Distinct Inventions The opinion in *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970), undertook a "restatement of the law of double patenting as enunciated by this court." To summarize it, the opinion says that

the first question is: Is the same invention being claimed twice? If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting. The court was speaking, of course, about the PTO rejection of a pending patent application intended to forestall double patenting. If the rejected claim defines *more* than an obvious variation, it is *patentably distinct.*
One of our most recent double patenting decisions is *In re Braat* , 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991) in which we held:

Thus, a double patenting rejection is sustainable here only if claims 5/1 and 6/1 of Dil are not *patentably distinct* from the subject matter defined by the rejected claims of Braat. . . . [The claim numbers refer to dependent claims 5 and 6, both depending from claim 1.]

. . . .

. . . [W]e conclude that the claims of the Braat application and the Dil patent *are patentably distinct,* and that *the double patenting rejection was in error.*

Id. at 594, 19 USPQ2d at 1293 (emphasis added). With respect to extension of patent protection we said in *Braat:*

It is true that allowance of the Braat application will result in some timewise extension of Philips' patent protection of the Dil structure. This is because Braat's claims *dominate* the invention of Dil claims 5/1 and 6/1. As our predecessor

court pointed out in *Borah,* in analogizing the *Stanley* decision, "We see . . . that *as a matter of law the extension of protection objection is not necessarily controlling."*
Id.(emphasis added). Just a fortnight before *Braat* we decided *Symbol Technologies Inc. v. Opticon, Inc* ., 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991), in which the court said:

Furthermore, even if there had been a breach of the restriction requirement, we would reject Opticon's argument on the *ultimate* obviousness-type double patenting *inquiry:* whether the claims of the '186 patent are *patentably distinct* from the claims of the '297 patent. *See In re Borah* , 354 F.2d 1009, 1017, 148 USPQ 213, 220 (CCPA 1966) (crux of obviousness-type double patenting inquiry lies in comparison of claims). . . .
Id. at 1580, 19 USPQ2d at 1249 (emphasis added).
[3] The extensive opinion in *In re Borah,* 354 F.2d 1009, 148 USPQ 213 (CCPA 1966), in its concluding pages, shows beyond question that the determining factor in deciding whether or not there is double patenting is the existence vel non of *patentable difference* between two sets of claims. The phrases actually used in the opinion include "patentably distinguishable," "patentable distinctions," and "whether such differences would have been obvious to one of ordinary skill in the art." They are all equivalent. The opinion summarizes two earlier cases, spanning three decades, to the same effect, citing

them as established law with full approval, namely, *In re Stanley*, 214 F.2d 151, 102 USPQ 234 (CCPA 1954), and *In re Calvert*, 97 F.2d 638, 38 USPQ 184 (CCPA 1938).

Before leaving *Borah* , we call attention to the following statement there made in the court's discussion of *Stanley*:

In *Stanley* , this court sanctioned, in 1954, the issuance of a dominating patent to the owner of the improvement patent which had issued in 1950, notwithstanding the owner's protection would thereby be extended beyond the expiration of the improvement patent by several years. We see, therefore, that as a matter of law the extension of protection objection is not necessarily controlling.

354 F.2d at 1017, 148 USPQ at 220.

We find in the facts of the instant case a parallel situation. The facts here indicate that in the commercial decaffeination of raw coffee the processor is interested, for economic reasons, not only in the effective decaffeination of raw coffee but in the effective recovery of pure caffeine as a by-product. Therefore, both of Zosel's inventions are preferably used in the same commercial process. These patentably distinct process inventions are covered by separate patents, however, which happen to expire at different times. Each process, nevertheless, is capable of being used by itself. The fact that it may be desirable to use both inventions in the same commercial process does not result, however, in any recognized form of double patenting, or in the "extension" of either patent; each patent has a term of seventeen years.

A licensee which has taken a license under both patents, choosing to use the inventions claimed in both patents in the same commercial process, must know that, in the absence of some agreement to the contrary, it is not excused from paying royalty after one of the patents expires while the other is still in force and the invention it claims is being used. In the 1978 exclusive license agreement entered into by GF and SGK, the licensed "Patent Rights" were set forth in a schedule of some 21 U.S. and foreign patents and applications with a wide range of expiration dates. Included therein are patent '619 which had issued in 1974 and both the parent and CIP applications, Serial Nos. 110,428 and 364,190 which resulted in the '639 patent in suit in 1981. The record shows that before the license was entered into, GF had been supplied with copies of the parent and CIP application prosecution histories and was therefore fully informed about aspects of the '639 prosecution history it now attempts to use to show invalidity on double patenting grounds, particularly the decision to file the CIP application which GF now depicts as a deliberate effort by SGK to "extend" its protection by obtaining "a 24-year patent," to cover the inventions of others, etc. It has to be considered a bit odd that after enjoying the benefits of a license to use the principal invention which caused it to take a license in 1978 -- the *decaffeination process* which it knew was not yet patented, not the caffeine recovery "improvement" which it no longer wishes to use -- and although fully informed about the prosecution of the patent on that decaffeination invention, it comes up with the contention a decade later that that patent is invalid and files the present declaratory judgment suit in 1988 to test its theory. At least, it would seem odd but for the realization that if its theory can be put across, it will save GF a lot of money. During the time GF was an *exclusive* licensee, its interest in having the broadest and longest patent protection on the decaffeination process was as great as SGK's.

Determining What Is Patented By Correct Claim Interpretation Is Essential To Determination of Obviousness-Type Double Patenting Issues

[4] The basic concept of double patenting is that the *same* invention cannot be patented more than once, which, if it happened, would result in a second patent which would expire some time after the original patent and extend the protection timewise. But double patenting law has always been more inclusive. Double patenting law principles extend to merely obvious variants *of what has been patented* . Step one of the analysis is to determine what that is. Claims are the determinants.

In the cases, which are mostly from the Court of Customs and Patent Appeals, now merged with the former Court of Claims to form this court, the development of the law came to a turning point in *In re Zickendraht,* 319 F.2d 225, 138 USPQ 22 (CCPA 1963), particularly in the concurring opinion therein. Soon thereafter the obvious variant kind of double patenting came to be known as "obviousness-type" double patenting, which signifies that the difference between the first-patented invention and its variant involves only an *unpatentable* difference, no second *patentable* invention having been made. The *Zickendraht* concurring opinion suggested that an obviousness-type double patenting situation could be overcome by filing a terminal disclaimer, which had been provided for in section 253 of the 1952 patent act for that very purpose. However, where the two inventions are *patentably distinct,* no disclaimer is called for. Where there is a second patentable invention, as there is here, because the difference is not an obvious one, it is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference. This was not done by the trial court. Rather, it was carefully misguided by GF's arguments into doing exactly the opposite, as we shall now show.

It should suffice, we feel, to point out the principal error into which the trial court was led which resides in a complete misinterpretation of claim 1, set forth above, of the '619 patent on the caffeine recovery process, now expired. We have quoted above, immediately following claim 1 of the '619 patent, Conclusion of Law 24 which is the ultimate error. The gist of it is that claim 1 of patent '639 in suit is "obvious from claim 1(a)" of patent '619. Of course, there is no such thing as "claim 1(a)," a term used no less than 11 times throughout the Findings of Fact and Conclusions of Law. There is a claim 1 and the *first step* of its 9 recited steps is designated "(a)." And that step recites the essence of the very same process claimed in the '639 patent in suit but, in accordance with the principles of claim construction discussed early in this opinion, *step (a) is not "claimed"* in the '619 patent, nor is it "patented" or "covered" as the trial court seems to have thought it was as shown by its Finding of Fact 58 which says: "It was obvious to one of ordinary skill in the art that supercritical carbon dioxide would substantially decaffeinate coffee, *as otherwise it would not be claimed in claim 1 of the '619 patent . . . .*" (Emphasis ours.) This concept violates the fundamental rule of claim construction, that what is claimed is what is *defined by the claim taken as a whole,* every claim limitation (here each step) being material. What is patented by claim 1 of '619 is

a 9- step caffeine recovery process, nothing more and nothing less.

A further error of the trial court in dealing with the '619 patent's claim 1 was in looking, *not* at what invention it *defines,* but at whatever the claim *discloses,* illustrated by Findings of Fact 68 and 69.

68. There cannot be double patenting here unless the plaintiff [GF] establishes, *inter alia,* that claims 1 and 4 of the '639 patent are obvious from the claims of the '619 patent, as interpreted by the specification in view of the prior art.

This is perfectly sound law if one construes "from the claims" to mean from the invention defined by the claims, but in the next finding the court jumps the track (emphasis ours):

69. *Claim 1(a)* of the '619 patent *anticipates,* or at least *renders obvious,* the inventions of claims 1 and 4 of the '639 patent *because every step of claims 1 and 4 of the '639 patent is set forth in claim 1(a)* of the '619 patent. . . .

This clearly is using nothing but the *disclosure* of clause (a) of claim 1 as though it were prior art, and in not reading claim 1 to determine what invention it *defines* -- like the metes and bounds of a deed. We repeat, clause (a) of claim 1 is not a claim, patent '619 does not claim clause (a) but a 9-step process of which (a) is the first step, and double patenting is based entirely on *what* is claimed, reading each claim as an entirety to determine what invention it defines.

A further illustration of the same misconstruction of claims by reading them for what

they *disclose* rather than to determine what they *define* appears in Conclusion of Law 18 which says, in part, "in this case the only relevant inquiry is whether the claims of the first patent ' *disclose* [ ] to one of ordinary skill in the art' the claims of the second patent." (Emphasis ours.) The source of the quoted phrase is not given. The court failed to observe the distinction between a claim as a written disclosure and a claim as a definition of an invention.

How the meaningless, confusing, and highly misleading expression "claim 1(a)" got injected into this case "is a puzzlement." We are also perplexed as to what the trial court meant by it in its constantly reiterated use. There is some evidence the court was led to believe that clause (a) of claim 1 was actually a claim in the sense that the words "claim" and "claimed" are used in the law of double patenting and in patent law generally. If that is so, we express sincere sympathy for the trial judge in his efforts to understand this double patenting issue, a subject usually fraught with difficulty. There is a much stronger indication that GF's counsel are responsible for the use of the term "claim 1(a)." Whether they originated it or not, they have perpetuated it in the course of ten pages of their brief before this court (Main Brief at pages 39-49, the term appearing at least once on every page except page 47 and altogether 17 times). This fictitious "claim 1(a)," which is supposed to define some already patented invention, is then argued to make the invention claimed in the patent in suit obvious, if not anticipated which is the epitome of

obviousness. This may seem plausible because "claim 1(a)" is a description of that very invention. But, in the first place, this argument fails because it totally ignores the rules of claim interpretation and, in the second place, it is used as though it is a prior art disclosure for everything recited in claim 1 being applied to support an obviousness rejection under 35 USC 103. This is impermissible in the law of double patenting.

Precedents Prohibit Use of Disclosure of Patent Cited to Support Double Patenting

[5] Our precedent makes clear that the *disclosure* of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, *even where the disclosure is found in the claims. See, e.g., Braat*, 937 F.2d at 594 n.5, 19 USPQ at 1293 n.5 ("The patent disclosure must not be used as prior art"); *Vogel*, 422 F.2d at 442, 164 USPQ at 622 (in considering obviousness-type double patenting, "the patent disclosure may not be used as prior art"); *In re Plank* , 399 F.2d 241, 242, 158 USPQ 328, 329 (CCPA 1968) ("Its claims [Plank et al. patent] are used as the basis for a double patenting rejection. It is not a prior art reference"); *In re Aldrich,* 398 F.2d 855, 859, 158 USPQ 311, 314 (CCPA 1968) ("double patenting rejections *cannot* be based on section 103, . . . or on the disclosures of the patents whose claims are relied on to demonstrate double patenting or on the 'disclosures' of their claims. . . . [P]atent claims are looked to only to see what *has been patented,* the subject matter which *has been protected,* not for something one may find to be disclosed by reading them"); *In re Boylan,* 392 F.2d 1017, 1018 n.1, 157 USPQ 370, 371 n.1 (CCPA 1968) ("in analyzing cases of these types, it must always be carefully observed that the appellant's patent is not 'prior art' under either section 102 or section 103 of the 1952 Patent Act"); *In re Braithwaite,* 379 F.2d 594, 600 n.4, 154 USPQ 29, 34 n.4 (CCPA 1967) ("While analogous to the non-obviousness requirement of 35 U.S.C. Section 103, that section is not itself involved in double patenting rejections because the patent principally underlying the rejection is not prior art"); *Borah,* 354 F.2d at 1018, 148 USPQ at 221 ("We have no prior art here"); *In re Sutherland,* 347 F.2d 1009, 1015, 146 USPQ 485, 491 (CCPA 1965) ("Nor is obviousness invariably involved in 'double patenting' rejections. Claims relied on in such [double patenting] rejections often disclose or name the *very thing* being claimed [in the rejected claims]. Furthermore, the words of such claims cannot be treated as 'prior art,' . . . but are looked to solely for the purpose of determining *what has already been patented.* They are not treated as prior art for the simple reason they are no more 'prior art' under the statute than the specification") (citation omitted); *In re Sarett,* 327 F.2d 1005, 1013, 140 USPQ 474, 481 (CCPA 1964) ("We are not here concerned with what one skilled in the art would be aware [of] from *reading* the claims but with *what inventions the claims define.*")

The '619 Patent During Its Term Provided No Protection for the Invention Claimed in the '639 Patent

Double patenting is intended to prevent unjustified *extension* of protection. Because the trial court misunderstood the construction of patent claims, it failed to appreciate that the *invention* of the second-to-issue '639 patent received *no* protection from the first-issued '619 patent because no claim of the latter covers the decaffeination process. Pro

tection of that invention did not begin until the '639 patent issued on April 7, 1981. It will expire 17 years thereafter. There is no 24-year patent protection as GF alleges.

All that is claimed in the '619 patent is the caffeine recovery invention. To clearly understand this one must look at all the claims of '619. There are only 6 claims and the broadest is independent claim 4 which we quote as showing the maximum patent coverage of this patent:

4. A process for concentrating a dilute aqueous solution of caffein, which comprises:

a. introducing the dilute aqueous solution into an evaporating zone, passing a stream of air or nitrogen through the aqueous solution in the evaporating zone for evaporating of water from the aqueous solution and concentration of caffein in the aqueous solution, and withdrawing a concentrated aqueous solution from the evaporating zone,

b. withdrawing the air or nitrogen laden with water vapor from the evaporating zone and cooling it for condensation of water and separating the water from the gas in a separating zone,

c. circulating the air or nitrogen between the evaporating zone and the separating zone,

d. admixing the dilute aqueous solution of caffein and the air or nitrogen conveyed from the separating zone to the evaporating zone,

e. passing the air or nitrogen laden with water vapor and the admixture formed in step (d) in indirect heat exchange relation between the evaporating zone and the separating zone, for cooling of the air or nitrogen laden with water vapor for the condensation of step (b) and for heating said mixture for heating the aqueous solution for evaporation of step (a), and

f. supplying additional heat to the aqueous solution for the evaporation.

Comparison of this claim 4 with claim 1 will show the general correspondence of claim 4 to steps (d)-(j) of claim 1 which further references carbon dioxide in steps (d) and (g) and shows in steps (a)-(c) the source of the caffeine to be coffee which has been treated with moist supercritical carbon dioxide, making claim 1 more limited but still containing all the limitations of claim 4.

Since a patent is not infringed unless one or more claims are infringed and none of the '619 claims are infringed by one practicing the decaffeination process claimed in patent '639 without more, the '619 patent did not cover the '639 process and a patent thereon cannot extend the protection granted by the now expired '619 patent.

As the '619 patent states in its second paragraph, previously quoted herein, the recovery of the caffein produced by the '639 patent is not described in that patent, which was then only the CIP application, Ser. No. 364,190. Furthermore, by these statements in the '619 patent the public was put on notice of the existence of the CIP application's pendency, of the invention therein described, and the probability of a future patent.

Other Arguments

Both parties' briefs have made and debated, and we have considered, numerous arguments other than those we have discussed, the majority of which we find irrelevant and all of which we find it unnecessary to comment on.

CONCLUSION

Finding the judgment of the District Court that claims 1 and 4 of the '639 patent are invalid for obviousness-type double patenting in view of claim 1 of the '619 patent to have been in error, essentially because of the distressing failure to adhere to firmly established and universally understood rules of claim interpretation, that judgment is reversed and the case is remanded for further proceedings.

COSTS

(a) Appellant requests us to vacate the award of costs on the double patenting trial. We deny the request and leave it to the trial court to review and decide in view of the outcome.

(b) Costs on this appeal to appellant.

REVERSED AND REMANDED

Footnotes

Footnote 1. Two spellings of "caffeine" appear in this opinion because the '619 patent omits the terminal "e" except in its title.

- End of Case -

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All Other Cases

Atlas Powder Company v. E.I. Du Pont De Nemours & Company (CA FC) 224 USPQ 409 Atlas Powder Company v. E.I. Du Pont De Nemours & Company

U.S. Court of Appeals Federal Circuit
224 USPQ 409

Decided Dec. 27, 1984
No. 84-504

Headnotes

PATENTS

1. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Use of prophetic examples does not automatically make patent nonenabling, burden being on patent challenger to show by clear and convincing evidence that prophetic examples together with specification's other parts are nonenabling.

2. Infringement -- In general (§ 120.01)

Where accused has appropriated material features of patent, infringement will be found even when those features have been supplemented and modified to such extent that accused may be entitled to patent for improvement.

3. Infringement -- Doctrine of equivalents -- In general (§ 120.0701)

Patentee that was unable effectively to use product that accused successfully developed, is not estopped from asserting infringement on equivalence theory, since focus in assessing equivalence is on whether accused's product performs substantially same as claimed product in function, way and result, and not on patentee's ability to devise product equivalent to patented product.

Particular patents -- Explosives

3,447,978, Bluhm, Ammonium Nitrate Emulsion Blasting Agent and Method of Preparing Same, decision holding claims 1-5, 7, 12-14, and 16-17, valid and infringed, affirmed.

Case History and Disposition:

Appeal from District Court for the Northern District of Texas, Higgenbotham, J.; 221 USPQ 426 **.**

Action by Atlas Powder Company, against E.I. Du Pont De Nemours & Company, and Alamo Explosives Company, Inc., for patent infringement, in which defendant counterclaims for declaration of patent invalidity. From Judgment for plaintiff, defendants appeal. Affirmed.

Attorneys:

Garland P. Andrews, Roy W. Hardin, David L. Hitchcock, and Richards, Harris & Medlock, all of Dallas, Tex., for plaintiff.

Stanley Neely, and Locke, Purnell, Boren, Laney & Neely, both of Dallas, Tex., and Lawrence F. Scinto, Nels T. Lippert, and Fitzpatrick, Cella, Harper & Scinto, all of New York, N.Y., for defendants.

Judge:

Before Markey, Chief Judge, and Baldwin and Miller, Circuit Judges.

Opinion Text

Opinion By:

Baldwin, Circuit Judge.

This is an appeal by E. I. du Pont De Nemours & Co. and its customer Alamo Explosives Co., Inc. (collectively, "Du Pont"). The appeal is from a final judgment of the United States District Court for the Northern District of Texas holding product claims 1-5, 7, 12-14, and 16-17 of U.S. Patent No. 3,447,978 ('978 patent), issued to Harold Bluhm on June 3, 1969 and assigned to the Atlas Powder Co. ("Atlas"), not invalid under 35 U.S.C. §§ 102, 103 and 112, not fraudulently procured, and infringed. We affirm.

Background

The district court opinion, reported at 588 F.Supp. 1455, 221 USPQ 426 (1983), contains a detailed description of the facts, familiarity of which is presumed herein.
Briefly, the '978 patent relates to blasting agents, i.e., chemical mixtures that are relatively insensitive to normal modes of detonation but can be made to detonate with a high strength explosive primer. By the mid-1960's, blasting agents consisted of two major types: "ANFO" and "water-containing."
An "ANFO" blasting agent comprised a mixture of particulate ammonium nitrate, usually in the form of small round aggregates known as "prills," and fuel oil (e.g., diesel fuel). They were widely used in mining and construction because of their low cost, ease of handling, and ability to be mixed at the blast site rather than prepackaged at the plant. However, to work properly they could be used only in "dry" holes (without water) because water desensitized the mixture, rendering it nondetonable.
A "water-containing" blasting agent, which was water resistant, generally comprised a slurry of particulate ammonium nitrate (or other oxidizing salt), a solid or liquid fuel, at least 5 percent water, and, as a sensitizer to increase explosive power, either a high explosive such as TNT or a chemical

such as nitric acid. Often, a gelling agent was added, particularly in the chemical sensitized slurries, to prevent the separation of sensitizers from slurry by forming a gel (a colloid in which the disperse phase has combined with the continuous phase to produce a viscous, jelly-like product). The use of sensitizers in water-containing blasting agents made preparation and handling more difficult and dangerous and, hence, more costly.
Before the '978 invention, Atlas manufactured a gelled slurry blasting agent called Aquanite, based on U.S. Patent No. 3,164,503, issued to Gehrig and assigned to Atlas. Aquanite used as a sensitizer nitric acid, which was highly caustic to skin and clothing and tended to separate out of the product even in the presence of a gelling agent, thereby reducing the product's stability and shelf life. Also, Aquanite was "hypergolic," i.e., it ignited wood, coal and various chemicals upon contact, which was suspected of causing the blasting agent to detonate prematurely.

The Invention

In 1965, Atlas assigned Harold Bluhm to investigate stabilizing its Aquanite gel. Bluhm experimented with various "emulsions" that did not contain nitric acid or a gelling agent. (An emulsion is a stable mixture of two immiscible liquids; a "water-in-oil" emulsion has

a continuous oil and discontinuous aqueous phase; an "oil-in-water" emulsion is the reverse.) In early 1966, Bluhm formulated an intimately mixed water-in-oil, water resistant emulsion blasting agent. The product was sensitized with entrapped air rather than high explosives or chemicals and is the subject matter of the claims at issue. Representative is Claim 1:

1. An emulsion blasting agent consisting essentially of:
an aqueous solution of ammonium nitrate forming a discontinuous emulsion phase;
a carbonaceous fuel forming a continuous emulsion phase;
an occluded gas dispersed within said emulsion and comprising at least 4% by volume, thereof at 70°F. and atmospheric pressure; and
a water-in-oil type emulsifying agent;
said carbonaceous fuel having a consistency such that said occluded gas is held in said emulsion at a temperature of 70°F.

Claim 1 is the only independent claim in suit. The other, dependent claims describe various ingredients, such as miscrospheres for the occluded gas, additional fuels (e.g., aluminum), specific ranges of ingredients, and various properties of the blasting agent.

Du Pont's Activities

Du Pont sold a gelled slurry blasting agent until the latter part of the 1970's. In 1976, Du Pont formed a team to study the feasibility of an emulsion blasting agent. The team succeeded in making a water-in-oil emulsion blasting agent which Du Pont began making and selling in August 1978. Atlas sued for infringement in December 1979.

The District Court Proceedings

A non-jury trial was held between January 28 and February 2, 1982. Du Pont asserted invalidity of the '978 patent under sections 102(a), 103, and 112, "fraud" on the Patent and Trademark Office (PTO), and noninfringement. The district court rejected those assertions for the product claims at issue, holding that: (1) the claimed invention was not anticipated by the prior art; (2) the claimed invention would not have been obvious in view of the prior art; (3) the claims were not invalid for the patent's failure to comply with the "best mode," enablement, and "overclaiming" requirements of 35 U.S.C. §112; (4) the patent was not procured by "fraud" on the PTO; and (5) Du Pont's products infringed the claims under the doctrine of equivalence. On appeal, Du Pont contests those holdings, except for the one on best mode.

The district court denied Atlas increased damages and attorney fees because Du Pont had not willfully infringed the '978 patent claims and the case was not "exceptional." The district court also held that product claims 6, 13, and 15 were not infringed and that process claims 18-30 were invalid. Atlas has not appealed those holdings.

Issues

(1) Whether the district court was clearly erroneous in finding the invention of the patent claims at issue not anticipated by the prior art.
(2) Whether the district court erred in holding that the invention of the patent claims at issue would not have been obvious.
(3) Whether the district court erred in holding the patent claims at issue not invalid because of nonenablement.

(4) Whether the district court erred in holding no "fraud" on the PTO; i.e., no inequitable conduct.

(5) Whether the district court was clearly erroneous in finding that Du Pont's products infringed the '978 claims under the doctrine of equivalents.

Opinion

I. Standard of Review

The burden is on Du Pont, as appellant, to establish that the district court's ultimate fact findings (e.g., anticipation, infringement) were clearly erroneous, that the district court's legal conclusions (e.g., §103 obviousness, §112 enablement) were erroneous, or that the findings underlying the ultimate findings or conclusions were clearly erroneous. The "clearly erroneous" standard is satisfied if we are left with the firm conviction that error has been committed. See, e.g., Raytheon Co. v. Roper Corp., 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), cert. denied, 53 U.S.L.W. 3255 (U.S. Oct. 2, 1984).

II. Presumption of Validity

Under 35 U.S.C. §282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984), cert. denied, 53 U.S.L.W. 3225 (U.S. Oct. 2, 1984). In that regard, the district court committed an error.

After correctly stating that the presumption of validity must be overcome with clear and convincing evidence, the district court stated that, if pertinent prior art were not cited to the PTO, as was the case here, the presumption is weakened and Du Pont must prove invalidity by only a preponderance of the evidence. That is incorrect. Though the introduction of prior art not before the PTO may facilitate meeting the challenger's ability to meet the burden of proof on invalidity, the presumption remains intact, the burden of persuasion remains on the challenger, and the "clear and convincing" standard does not change. See, e.g., Jervis B. Webb Co. v. Southern Systems, Inc., 742 F.2d 1388, 1392 & n.4, 222 USPQ 943 , 945 & n.4 (Fed. Cir. 1984); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534, 218 USPQ 871, 875 (Fed. Cir. 1983).

The error, however, was harmless. Indeed, it helped Du Pont at trial by lowering the standard of proof needed to prove its case. Even with the lower standard, Du Pont was unable to succeed.

III. Anticipation

The district court's determination of no anticipation was a factual one that should be reversed only if appellant shows that it was clearly erroneous. See, e.g., Lindemann Machinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984). Du Pont attempts to satisfy its burden by arguing that U.S. Patent No. 3,161,551, to Egly, et al., anticipated the claimed invention. We conclude, however, that the district court's finding of no anticipation was not clearly

erroneous.
Egly, which Du Pont referred to at oral argument as the "closest prior art," describes an emulsion of ammonium nitrate, water, fuel oil, and water-in-oil emulsifying agent. Though Egly teaches the presence of solid ammonium nitrate prills as an essential ingredient, Du Pont argues that the '978 claims, because of the phrase "consisting essentially of," does not exclude the presence of those prills. See, e.g., In re Herz, 537 F.2d 549, 551, 190 USPQ 461, 463 (CCPA 1976); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). Du Pont is correct. However, the district court found that Egly "does not mention air or gas as an ingredient in their explosives" and occluded air is an element of the claims. Hence, there is no anticipation under §102, because the exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771-72, 218 USPQ 781, 789 (Fed. Cir. 1983).
Du Pont asserts that Bluhm conceded in answer to an interrogatory that the first reduction to practice of the claimed invention was on January 14, 1966, and that Mr. Bluhm's notebook shows the composition prepared on that date to be identical to Egly's i.e., an emulsion without occluded air. Because the first reduction to practice was identical to Egly's product, Du Pont argues, the claimed invention is anticipated by Egly. Atlas argues that the notebook entry reveals that occluded air was present in the composition prepared on January 14, 1966, and hence, the first reduction to practice was not identical to Egly's composition. Atlas appears to be correct but, in any event, the district court's anticipation analysis properly focused on the claimed invention, which includes occluded air, not on Atlas' characterization of the January 14, 1966 experiment as the first reduction to practice.

IV. Obviousness

Though an invention is not anticipated by 35 U.S.C. §102, a patent should not issue if the differences between the claimed invention and prior art are such that the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. 35 U.S.C. §103. In assessing nonobviousness a court should answer certain factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) so-called "secondary" considerations, e.g., long felt need, unexpected results, commercial success. See, e.g., Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d at 1538, 218 USPQ at 876; Simmons Fastener Corp. v. Illinois Tool Works, Inc., 739 F.2d 1573, 1575, 222 UPSQ 743, 746 (Fed. Cir. 1984). The "secondary" considerations, when present, may assist the court in determining nonobviousness without falling prey to hindsight reasoning.
Here, the district court made findings on the content of the prior art, the level of ordinary skill in the art, the differences between the prior art and the claimed invention as a whole, and then concluded that the claimed invention was nonobvious. Du Pont has not shown error in the legal conclusion of nonobviousness, or clear error in the underlying findings.

Content of the Prior Art and Differences Between It and the Claimed Invention

In addition to Egly, discussed above, the district court considered several patents and articles.

Atlas' Gehrig patent describes a blasting agent containing particulate ammonium nitrate, a solution of nitric acid in water, and fuel oil. Though the mixture may be an emulsion, the primary thrust of Gehrig is using a gel. Gehrig notes that, when an emulsion is used, the product quickly separates into its various components. Gehrig recommends that the emulsion be used within 24 hours to avoid separation. The gel form is considered desirable to stabilize the product for storage.

The claimed invention differs from Gehrig because Gehrig requires nitric acid as an essential ingredient. The '978 claims exclude the presence of nitric acid because the essence of the claimed composition is the elimination of nitric acid and the claim phrase "consisting essentially of" excludes ingredients that would "materially affect the basic and novel characteristics" of the claimed composition. In re Herz, 537 F.2d at 551, 190 USPQ at 463; In re Janakirama-Rao, 317 F.2d at 954, 137 USPQ at 895.

Gehrig does not teach substituting nitric acid with air to sensitize the product. Though it suggests the use of microballoons containing air as a stabilizer, it also discusses heating the product to remove entrapped air.

U.S. Patent No. 3,052,578, to Davis, describes a blasting agent comprising a blend of fuel oil and ammonium nitrate poured over solid ammonium nitrate. An oil-in-water, not water-in-oil, emulsifying agent is suggested to disperse the fuel. Though an emulsifying agent is used for dispersing purposes, the reference does not discuss forming an emulsion, and it does not suggest use of occluded air.

Two papers by Coxon relate to water resistant blasting agents. The first describes a water-in-oil emulsion of fuel oil and ammonium nitrate poured over solid ammonium nitrate. The second is similar, but prefers an oil-in-water emulsifying agent. Neither paper teaches the presence of occluded air; instead, the blasting agent requires solid ammonium nitrate. Thus, both Coxon papers, as well as Davis, are similar to Egly.

U.S. Patent No. 3,004,842, to Rowlinson, describes melting solid ammonium nitrate and mixing it with fuel oil and an emulsifying agent to form a solid blasting agent. A small amount of water may be added to reduce the melting point of the ammonium nitrate. Foaming agents can be added to increase the product's sensitivity.

U.S. Patent No. 3,453,158, to Clay, describes a gel or thickened slurry containing aqueous ammonium nitrate, a gelling agent or thickener, air bubbles serving as a sensitizer, and particulate fuels or sensitizers. The district court found that Clay does not use an emulusion, let alone a water-in-oil emulsion, and that finding has not been shown to be clearly erroneous.

Level of Skill in the Art

The district court found that the person of ordinary skill in the art would be one skilled in the art of explosives formulation, having knowledge of and experience with the chemical and physical properties of explosives. The person should be a chemist or chemical engineer with at least a bachelor's degree and several years of practical experience. Also, he or she should have a working knowledge of the principles of emulsion chemistry as

applied to explosives formulation.

" *Secondary" Considerations*

The district court stated that, in light of "substantial differences" between the prior art and the product claims, it is not necessary to consider secondary factors, though they were raised by Atlas. Hence, the district court's opinion does not contain a section on "secondary criteria" or otherwise attempt to identify such criteria under the label. Nevertheless, the district court found that "[t]he Bluhm patent solved the problem of finding a water resistent ANFO blasting agent that did not require chemical sensitizers." Moreover, the district court in essence found that the solution to the problem was unexpected.

Though the prior art describes water-in-oil emulsions containing dissolved ammonium nitrate, fuel oil, and a water-in-oil emulsifying agent, the district court found that the art does not suggest that the emulsion itself can serve as a blasting agent. Egly, for example, teaches that such an emulsion -- without occluded air -- serves as a sensitizer that can be poured over solid ammonium nitrate to form a blasting agent. Gehrig teaches that the emulsion serves as a blasting agent only in the presence of nitric acid. That the Egly sensitizer itself serves as a blasting agent when occluded air is added, or that the Gehrig blasting agent could serve in that capacity without nitric acid, was unexpected. Though occluded air was recognized as an ingredient that could be included in blasting agent compositions, e.g., to stabilize the nitric acid containing product of Gehrig, the district court found that the references simply did not teach "that aeration can substitute for chemical sensitizers [e.g., nitric acid] in slurry explosives or that a water-in-oil emulsion is the most efficient system for entraining air."

Moreover, the district court found (and it has not been shown to be clearly erroneous) that the references cited by Du Pont deemphasize occluded air in emulsions and, hence, teach away from the importance of aeration. Egly and Davis do not mention air or gas as an ingredient in their explosives, and one of the Coxon papers teaches that detonation performance may be improved by using emulsifiers to eliminate frothing (air) from explosives.

Conclusion on Nonobviousness

In light of the differences between the claimed invention and prior art, the '978 solution to a troublesome problem, and the unexpected result that a water-in-oil emulsion of ammonium nitrate, fuel oil, and a water-in-oil emulsifying agent can serve as a blasting agent in the presence of occluded air, we agree with the district court's conclusion of nonobviousness.

Du Pont argues that it would have been obvious in 1966 to leave the nitric acid sensitizer out of Gehrig's slurry, intimately mix the fuel oil and ammonium nitrate, and sensitize the product in some other way, e.g., with air. We agree with the district court, however, that neither Gehrig nor the other prior art suggests those changes to obtain an emulsion blasting agent. As stated by the district court:

It is quite a leap from recognition that dry ANFOs could be sensitized by aeration to

realization that if an ANFO slurry was placed in the proper form of a water-in-oil emulsion and aerated, it would not require chemical sensitizers for detonability. This leap would not have been obvious in 1966.

V. Enablement

The district court rejected Du Pont's arguments of "overly broad," "overclaiming," and "non-enablement," and its argument that the broad scope of the claims is not supported by the limited disclosure present. In essence, those arguments are one: the '978 disclosure does not enable one of ordinary skill in the art to make and use the claimed invention, and hence, the claimed invention is invalid under 35 U.S.C. §112, ¶1.

To be enabling under §112, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. Raytheon Co. v. Roper Corp., 724 F.2d at 960, 220 USPQ at 599. That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive. See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983), cert. denied, 53 U.S.L.W. 3226 (U.S. Oct. 2, 1984); In re Angstadt, 537 F.2d 498, 503, 190 USPQ 214, 218 (CCPA 1976). Determining enablement is a question of law. Raytheon Co. v. Roper Corp., 724 F.2d at 959-60, 220 USPQ at 599.

Du Pont argues that the patent disclosure lists numerous salts, fuels, and emulsifiers that could form thousands of emulsions but there is no commensurate teaching as to which combination would work. The disclosure, according to Du Pont, is nothing more than "a list of candidate ingredients" from which one skilled in the art would have to select and experiment unduly to find an operable emulsion.

The district court held it would have been impossible for Bluhm to list all operable emulsions and exclude the inoperable ones.

Further, it found such list unnecessary, because one skilled in the art would know how to select a salt and fuel and then apply "Bancroft's Rule" to determine the proper emulsifier. Bancroft's Rule was found by the district court to be a "basic principle of emulsion chemistry," and Du Pont has not shown that finding to be clearly erroneous.

We agree with the district court's conclusion on enablement. Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude * * * possible inoperative substances * * * *" In re Dinh-Nguyen, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1973). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971). That, however, has not been shown to be the case here.

Du Pont contends that, because the '978 examples are "merely prophetic," they do not aid one skilled in the art in making the invention. 1 Because they are prophetic, argues Du

Pont, there can be no guarantee that the examples would actually work.
[1] Use of prophetic examples, however, does not automatically make a patent non-enabling. The burden is on one challenging validity to show by clear and convincing evidence that the prophetic examples together with other parts of the specification are not enabling. Du Pont did not meet that burden here. To the contrary, the district court found that the "prophetic" examples of the specification were based on actual experiments that were slightly modified in the patent to reflect what the inventor believed to be optimum, and hence, they would be helpful in enabling someone to make the invention.
Du Pont argues that of some 300 experiments performed by Atlas before the filing of the '978 patent application, Atlas' records indicated that 40 percent failed "for some reason or another." The district court agreed that Atlas' records showed 40 percent "failed," but found that Atlas' listing of an experiment as a "failure" or "unsatisfactory" was misleading. Experiments were designated "failures," the district court found, in essence because they were not optimal under all conditions, but such optimality is not required for a valid patent. Decca Ltd. v. United Staes, 544 F.2d 1070, 1077, 191 USPQ 439, 444-45 (Ct. Cl. 1976). Accord, E. I. du Pont de Nemours & Co. v. Berkley & Co., 620 F.2d 1247, 1260, 205 USPQ 5, 10 (8th Cir. 1980). Cf. Raytheon Co. v. Roper Co., 724 F.2d at 958, 220 USPQ at 598. The district court also found that one skilled in the art would know how to modify slightly many of those "failures to form a better emulsion. Du Pont has not persuaded us that the district court was clearly erroneous in those findings.
Du Pont asserts that Atlas was able to produce suitable emulsions with only two emulsifiers, "Atmos 300" and "Span 80," and therefore, the disclosure should be construed to read upon only those two emulsifiers. However, Du Pont did not prove that the other disclosed emulsifiers were inoperable. The district court credited testimony by Atlas' expert, Dr. Fowkes, to the effect that he had successfully formed a number of detonable emulsions using a variety of emulsifiers specified in the '978 patent. Further, the district court found that one skilled in the art would know which emulsifiers would work in a given system. Indeed, the district court found that Du Pont's own researchers had little difficulty in making satisfactory emulsions with the emulsifying agents, salts, and fuels listed in the '978 patent. Those findings have not been shown to be clearly erroneous.
In sum, we conclude that Du Pont has failed to show that the district court erred in determining enablement.

VI. Inequitable Conduct

This court has held "inequitable conduct" in the PTO to be a more appropriate label than "fraud." J. P. Stevens & Co. v. Lex Tex Ltd., Nos. 84-754,-761, slip op. at 9, 223 USPQ 1089, 1092 (Fed. Cir. Nov. 9, 1984). Hence, this opinion will use the phrase "inequitable conduct" rather than "fraud."
Inequitable conduct requires proof by clear and convincing evidence of a threshold degree

of materiality of the nondisclosed or false information. That threshold can be established

by any of four tests: (1) objective "but for"; (2) subjective "but for"; (3) "but it may have been"; and (4) 37 C.F.R. §1.56(a), i.e., whether there is a substantial likelihood that a reasonable examiner would have considered the omitted or false information important in deciding whether to allow the application to issue as a patent. Slip op. at 10, 223 USPQ 1094. The PTO standard is the appropriate starting point because it is the broadest and most closely aligns with how one ought to conduct business with the PTO. Id.
Inequitable conduct also requires proof of a threshold intent. That intent need not be proven with direct evidence. It may be proven by showing acts the natural consequences of which are presumably intended by the actor. Id. Proof of deliberate scheming is not needed; gross negligence is sufficient. Gross negligence is present when the actor knew or should have known of the materiality of a withheld reference. Id. at 11, 223 USPQ at 1096. On the other hand, simple negligence, oversight or an erroneous judgment made in good faith is insufficient. Id.
Once the thresholds of materiality and intent are established as facts, the court must balance them and determine as a matter of law whether the scales compel a conclusion that inequitable conduct occurred. Id. If the court reaches that conclusion, it must hold the patent claims at issue unenforceable.
Du Pont argues that Atlas committed inequitable conduct by failing to tell the examiner that the examples were "prophetic" and, hence, in misleading the examiner into believing that the examples were actually performed. However, the district court found that the examples were written in the present tense to conform with the PTO requirements on prophetic examples. Moreover, the district court found that all but one of the examples were based on actual experiments and only slightly modified to reflect the inventor's notion of the most effective formulation. Consequently, the district court found, there was no intent on the part of Atlas to mislead the PTO. Du Pont has not shown those findings to be clearly erroneous. Even if intent could be inferred, and if the examples were prophetic but not disclosed to the examiner as such, Du Pont has not shown the nondisclosure to have been material, i.e., important to an exminer in allowing the patent to issue.
Du Pont asserts that Atlas' conduct cannot be distinguished from that in Grefco, Inc. v. Kewanee Industries, Inc., 499 F.Supp. 844, 208 USPQ 218 (D. Del. 1980), aff'd without publ. opinion, 671 F.2d 495 (3d Cir. 1981). We disagree. In Grefco, the patentee, to convince the examiner of the invention's superiority, presented "test results" based on tests that it knew never occurred, told the examiner the invention had been successfully tested when it had twice failed, and withheld information about those failures from the examiner. Intent and materiality were clearly established in Grefco, and the court in weighing the two factors held that there was inequitable conduct. That is not true here.
Du Pont argues that Atlas did not disclose its numerous "failures" and that it "padded" the disclosure with emulsifiers it knew would not work. The district court, however, found that Du Pont failed to prove that any of the emulsifiers were inoperative and the court found that the evidence on the "failed" experiments was not dispositive. Du Pont has not shown any clear error on the part of the district court in those findings.
Du Pont also alleges inequitable conduct in Atlas not disclosing to the examiner its Aquanite gel, the commercial version of the invention of its Gehrig patent. Though the district court found Aquanite to be "pertinent," it found no intent in the nondisclosure because Atlas had disclosed the Gehrig patent to the examiner. Du Pont has not shown

any clear error in that finding. Cf. Vandenberg v. Dairy Equipment Co., 740 F.2d 1560, 1568-69, 224 USPQ 195 (Fed. Cir. 1984). (Vandenberg disclosed a PX-15 device as prior art but failed to describe it as its own prior invention; the disclosure was held to be inconsistent with the intent necessary for inequitable conduct).

VII. Infringement

Literal Infringement

Determining infringement requires claim construction as a preliminary step. See, e.g., Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983). If properly construed claims read on the infringing product, there is literal infringement. Id. at 1571, 219 USPQ at 1142.

Du Pont's blasting agents are water-in-oil emulsions containing water, ammonium nitrate, fuel oil, occluded gas, and an emulsifying agent. Unlike the claimed invention, Du Pont uses as the emulsifying agent sodium oleate, which is formed in situ by adding sodium hydroxide and oleic acid to the other emulsion ingredients. Sodium oleate is normally an oil-in-water emulsifying agent but in the environment of the Du Pont product (i.e., a high salt concentration leading to

phase inversion), the sodium oleate acts as a water-in-oil emulsifying agent. The Du Pont product, and the in situ process of forming it, are the subject of U.S. Patent No. 4,287,100, issued to Owen and assigned to Du Pont.

The district court construed the '978 claim term "water-in-oil type emulsifying agent" as excluding compounds that normally function as oil-in-water emulsifying agents, e.g., sodium oleate. That claim construction prompted the district court to find no literal infringement. Atlas does not contest that finding and, for purposes of appeal, we accept it and the underlying claim construction.

Doctrine of Equivalents

A product that does not literally infringe can infringe under the doctrine of equivalents. Designed to protect a patentee from an infringer who appropriates the invention but avoids the literal language of the claims, the doctrine allows a finding of infringement when the accused product and claimed invention perform substantially the same function in substantially the same way to yield substantially the same result. Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 608-09, 85 USPQ 328, 330 (1950); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 900, 221 USPQ 669, 679 (Fed. Cir. 1984), cert. denied, 53 U.S.L.W. 3226 (U.S. Oct. 2, 1984). The district court found that the Du Pont products and the claimed invention are equivalent, and Du Pont has not shown that finding to be clearly erroneous. 2

The district court's opinion clearly delineates the Graver Tank tripartite test of substantially the same function, way, and result but then, adopting an analysis found in Ziegler v. Phillips Petroleum Co., 483 F.2d 858, 870, 177 USPQ 481, 487 (5th Cir.), cert. denied, 414 U.S. 1079, 180 USPQ 1 (1973), focuses on the "function, purpose, and quality" of the emulsifying agents of Du Pont and the claimed invention. That focus, argues Du Pont, was wrong because it ignored the Graver Tank tripartite test. We

disagree.
Though Graver Tank articulates the tripartite test of "function, way, and result," it also states that the doctrine of equivalence should not be the prisoner of a rigid formula. Moreover, Graver, which as here compared a claimed mixture with an accused mixture in which one ingredient of the claimed mixture was changed, stated:
"Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform."
Id. at 611, 85 USPQ at 331.
Such consideration makes sense. Where, as here, the accused product avoids literal infringement by changing one ingredient of a claimed composition, it is appropriate for a court to consider in assessing equivalence whether the changed ingredient has the same purpose, quality, and function as the claimed ingredient. If it does, the accused and claimed products should meet the Graver Tank tripartite test of "function, way, and result."
That the district court focused on the function, quality, and purpose of the emulsifying agents does not mean it ignored the basic tripartite test which it expressly referred to in the opinion, We infer from that express reference, and from the opinion as a whole, that the district court did in fact find that the "function, way, and result" test was satisfied. See ACS Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1582, 221 USPQ 929, 936 (Fed. Cir. 1984) (this court will infer findings that were obviously necessary to the court's opinion).
Du Pont argues that, because its emulsion product was patented after the '978 patent issued, its product avoids infringement by equivalence. According to Du Pont, " *so long as direct infringement is lacking* , the grant of a patent to an accused infringer constitutes a prima facie determination of non-equivalence and, accordingly, of non-infringement" (Du Pont's emphasis). Atlas disagrees. So do we.
Du Pont concedes that, if Atlas patents A + B + C and Du Pont then patents the improvement A + B + C + D, Du Pont is liable to Atlas for any manufacture, use, or sale of A + B + C + D because the latter directly infringes claims to A + B + C. Du Pont urges, however, that it is not liable for manufacture, use, or sale of patented improvement A + B + C', even though A + B + C' is "equivalent" to A + B + C. We reject Du Pont's attempted distinction. Whether Du Pont makes A + B + C + D or A + B + C', Du Pont has used the gist of Atlas' invention to devise a patentable composition. There is no compelling reason to hold Du Pont liable

for infringement in one instance but not the other. 3
[2] We agree with Bendix Corp. v. United States, 199 USPQ 203 (Ct. Cl. Trial Div. 1978), aff'd, 600 F.2d 1364, 204 USPQ 617 (Ct. Cl. 1979). There the trial judge said that where defendant has appropriated the material features of the patent in suit, infringement will be found "even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement." 199 USPQ at 221-22. Though Du Pont argues that cases from other courts support a contrary result, we are not bound by those cases and in any event find

them unpersuasive. 4
More persuasive is the reasoning of Herman v. Youngstown Car Mfg. Co., 191 F. 579, 584-85 (6th Cir. 1911). After finding equivalence, the court rejected appellant's contention that its receipt of a patent negates infringement:
A patent is not the grant of a right to make or use or sell. It does not, directly or indirectly, imply any such right. It grants only the right to exclude others. The supposition that a right to make is created by the patent grant is obviously inconsistent with the established distinctions between generic and specific patents, and with the well-known fact that a very considerable portion of the patents granted are in a field covered by a former relatively generic or basic patent, are tributary to such earlier patent, and cannot be practiced unless by license thereunder.
Another reason sometimes advanced for supposing that the structure of the second does not infringe the claim of the first patent is that the Patent Office has declared that a patentable difference exists. The premise is sound, but not the conclusion. In examining the second application, the Patent Office has no concern with the scope of the claim of the first, and does not and must not pay any attention thereto. It is concerned only with the early disclosure by the specification and drawings. Patentable difference does not of itself tend to negative infringement. It may just as well be based upon infringement, plus improvement; and improvement may lie in addition, simplification, or variance.
See also Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42, 3 USPQ 40, 44 (1929) (where there is substantiality of function, way, and result, infringement cannot be avoided by any presumptive validity attaching to the issuance of a patent to the infringer); Sure Plus Mfg. Co. v. Kobrin, 719 F.2d 1114, 1117 (11th Cir. 1983) (no presumption of non-infringement arises from the issuance of a patent to the infringer); Freeman v. Altvater, 66 F.2d 506, 512, 18 USPQ 186, 192-93 (8th Cir.), cert. denied, 290 U.S. 696 (1933) (the court after finding equivalence stated that the issuance of a patent merely raises a presumption of validity, not a presumption of non-infringement).
Du Pont contends that one skilled in the art in 1966 would not have known that the '978 and Du Pont products were equivalent. It is not a requirement of equivalence, however, that those skilled in the art know of the equivalence when the patent application is filed or the patent issues. That question is determined as of the time infringement takes place. In Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1365, 219 USPQ 473, 483 (Fed. Cir. 1983), this court held that devices changing the patented invention with advances developed subsequent to the patent could infringe under the doctrine of equivalents. See also American Hosp. Supply Corp. v. Travenol Labs., Inc., 745 F.2d 1, 9, 223 USPQ 577, 583 (Fed. Cir. 1984).
[3] Du Pont also argues that Atlas is "estopped" from asserting that the '978 claims cover the use of an oil-in-water emulsifier such as sodium oleate because Atlas was unable to use that type of emulsifier effectively. We reject Du Pont's argument on two grounds. First, finding equivalence is not inconsistent with a patentee's unsuccessful attempt to make the accused product. The focus in assessing equivalence is on whether the accused product performs substantially the same as the claimed product in function, way and result -- it is not on the patentee's ability to devise a product equivalent to the patented

product. Indeed, the patentee's incentive to devise an equivalent product is often less than a competitor's, which alone may account for the competitor's success and the patentee's failure in devising the equivalent product. See, e.g., Leesona Corp. v. Varta Batteries, Inc., 522 F.Supp. 1304, 1328, 213 USPQ 222, 241 (S.D.N.Y. 1981).
Second, the record submitted to this court makes no reference to any type of estoppel. That strongly suggests that estoppel was not raised before the district court. Bockoven v. Marsh, 727 F.2d 1558, 1566 (Fed. Cir. 1984). Because a party may generally not argue on appeal an issue not raised below, Weinar v. Rollform Inc., 744 F.2d 797, 804, 223 USPQ 369, 372 (Fed. Cir. 1984); Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1388, 219 USPQ 569, 575 (Fed. Cir. 1983), the estoppel argument is not properly before us.
Du Pont also argues that, because its product is formed in situ, it is different from the claimed product. It is the claimed product, however, not the process of forming it, that is involved. The district court found that the Du Pont emulsion, though it uses what is normally an oil-in-water emulsifier, "acts as a water-in-oil emulsifier," "caus[ing] a water-in-oil emulsion to form," and is otherwise substantially the same as the '978 emulsion. Those findings have not been shown to be clearly erroneous.
Du Pont further contends that the district court erred in considering the "heart of the invention" in its infringement analysis. We disagree. Although there is no legally recognized "essence" or "heart" of the invention in determining validity, W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 53 U.S.L.W. 3226 (U.S. Oct. 2, 1984), it can be applicable in a determination of infringement under the doctrine of equivalents. Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983). Moreover, the district court's "heart of the invention" analysis was supplemental to its finding that the Graver Tank tripartite test was satisfied.
Finally, Du Pont argues that the district court erred in not addressing in its opinion which of the individual claims are infringed. However, the district court specified the infringing claims in its judgment, and we review judgments, not statements in opinions. See, e.g., Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d at 1463, 221 USPQ at 489. Reviewing the judgment, we conclude that the district court did not commit clear error in finding infringement of the claims on appeal.

VIII. Conclusion

Having considered all of Du Pont's arguments, the district court's decision that the '978 patent claims on appeal (1-5, 7, 12-14, and 16-17) are not invalid under 35 U.S.C. §§102, 103, and 112, that there was no inequitable conduct before the PTO, and that the claims on appeal were infringed, is *affirmed* .

Footnotes

Footnote 1. The PTO Manual of Patent Examining Procedure (MPEP) §608.01(p)(D) (5th ed. 1983), states:

Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. Paper examples should not be described using the past tense.

Footnote 2. One of Du Pont's products includes aluminum, which is not present in representative claim 1. It is, however, present in dependent claim 14. Moreover, the addition of an ingredient by Du Pont does not necessarily avoid infringement of claim 1. See, e.g., Radio Steel & Mfg. Co. v. MTD Products, Inc., 731 F.2d 840, 848, 221 USPQ 657, 663-64 (Fed. Cir. 1984), cert. denied, 53 U.S.L.W. 3225 (U.S. Oct. 2, 1984); Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482, 221 USPQ 649, 653 (Fed. Cir. 1984).

Footnote 3. Of course, if A + B + C' were patented because of unexpected results, those unexpected results might prompt a finding of no equivalence. That finding, however, would exist because, under the Graver Tank tripartite test, the "results" achieved by the claimed and accused products would be substantially different. The district court in this case did not find any such unexpected results. Though it found that Du Pont's products were more stable than those of the '978 patent, that is not necessarily inconsistent with equivalence. Equivalence does not require that the claimed invention and accused product have identical results; the results can be substantially the same and the accused product can be an improvement. Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d at 901-02, 221 USPQ at 679-80; Decca Ltd. v. United States, 544 F.2d 1070, 1080-81, 191 USPQ 439, 448 (Ct. Cl. 1976).

Footnote 4. We are bound by opinions of our predecessor courts, the Court of Claims and CCPA. South Corp. v. United States, 690 F.2d 1368, 215 USPQ 657 (Fed. Cir. 1982).

- End of Case -

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In re Vaeck (CA FC) 20 USPQ2d 1438 In re Vaeck

U.S. Court of Appeals Federal Circuit
20 USPQ2d 1438

Decided October 21, 1991
No. 91-1120

Headnotes

PATENTS

1. Patentability/Validity - Obviousness - Combining references (§ 115.0905)

Rejection of claimed subject matter as obvious under 35 USC 103 in view of combination of prior art references requires consideration of whether prior art would have suggested to those of ordinary skill in art that they should make claimed composition or device, or carry out claimed process, and whether prior art would also have revealed that such person would have reasonable expectation of success; both suggestion and reasonable expectation of success must be founded in prior art, not in applicant's disclosure.

2. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (§ 115.0903.03)

Patent and Trademark Office has failed to establish prima facie obviousness of claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, since prior art does not disclose or suggest expression in cyanobacteria of chimeric gene encoding insecticidally active protein, or convey to those of ordinary skill reasonable expectation of success in doing so;

expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious expression of unrelated genes in cyanobacteria for unrelated purposes.

3. Patentability/Validity - Specification - Enablement (§ 115.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure - Judicial review - Standard of review - Patents (§ 410.4607.09)

Specification must, in order to be enabling as required by 35 USC 112, first paragraph, teach person skilled in art to make and use invention without "undue experimentation," which does not preclude some experimentation; enablement is question of law which is reviewed independently on appeal, although such determination is based upon underlying factual findings which are reviewed for clear error.

PATENTS

4. Patentability/Validity - Specification - Enablement (§ 115.1105)

Patent and Trademark Office did not err in rejecting, as non-enabling pursuant to 35 USC 112, first paragraph, claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, in view of relatively incomplete understanding of biology of cyanobacteria as of applicants' filing date, as well as limited disclosure by applicants of particular cyanobacterial genera operative in claimed invention, since there is no reasonable correlation between narrow disclosure in applicants' specification and broad scope of protection sought in claims encompassing gene expression in any and all cyanobacteria.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 07/021,405, filed March 4, 1987, by Mark A. Vaeck, Wipa Chungjatupornchai, and Lee McIntosh (hybrid

genes incorporating a DNA fragment containing a gene coding for an insecticidal protein, plasmids, transformed cyanobacteria expressing such protein and method for use as a biocontrol agent). From decision rejecting claims 1-48 and 50-52 as unpatentable under 35 USC 103, and rejecting claims 1-48 and 50-51 for lack of enablement, applicants appeal. Affirmed and part and reversed in part; Mayer, J., dissents with opinion.

Attorneys:

Ian C. McLeod, Okemos, Mich., for appellant.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor and Richard E. Schafer, associate solicitor, with him on brief), for appellee.

Judge:

Before Rich, Archer, and Mayer, circuit judges.

Opinion Text

Opinion By:

Rich, J.

This appeal is from the September 12, 1990 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), affirming the examiner's rejection of claims 1-48 and 50-52 of application Serial No. 07/021,405, filed March 4, 1987, titled "Hybrid Genes Incorporating a DNA Fragment Containing a Gene Coding for an Insecticidal Protein, Plasmids, Transformed Cyanobacteria Expressing Such Protein and Method for Use as a Biocontrol Agent" as unpatentable under 35 USC 103, as well as the rejection of claims 1-48 and 50-51 under 35 USC 112, first paragraph, for lack of enablement. We reverse the § 103 rejection. The § 112 rejection is affirmed in part and reversed in part.

BACKGROUND

A. *The Invention*

The claimed invention is directed to the use of genetic engineering techniques 1 for production of proteins that are toxic to insects such as larvae of mosquitos and black flies. These swamp-dwelling pests are the source of numerous human health problems, including malaria. It is known that certain species of the naturally-occurring *Bacillus* genus of bacteria produce proteins ("endotoxins") that are toxic to these insects. Prior art methods of combatting the insects involved spreading or spraying crystalline spores of

the insecticidal *Bacillus* proteins over swamps. The spores were environmentally unstable, however, and would often sink to the bottom of a swamp before being consumed, thus rendering this method prohibitively expensive. Hence the need for a lower-cost method of producing the insecticidal *Bacillus* proteins in high volume, with application in a more stable vehicle.
As described by appellants, the claimed subject matter meets this need by providing for the production of the insecticidal *Bacillus* proteins within host cyanobacteria. Although both cyanobacteria and bacteria are members of the procaryote 2 kingdom, the

cyanobacteria (which in the past have been referred to as "blue-green algae") are unique among procaryotes in that the cyanobacteria are capable of oxygenic photosynthesis. The cyanobacteria grow on top of swamps where they are consumed by mosquitos and black flies. Thus, when *Bacillus* proteins are produced within transformed 3 cyanobacterial hosts according to the claimed invention, the presence of the insecticide in the food of the targeted insects advantageously guarantees direct uptake by the insects.
More particularly, the subject matter of the application on appeal includes a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing 4 the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.
The claims on appeal are 1-48 and 50-52, all claims remaining in the application. Claim 1 reads:

1. A chimeric gene capable of being expressed in Cyanobacteria cells comprising:
(a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and
(b) at least one DNA fragment coding for an insecticidally active protein produced by a Bacillus strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein,
the DNA fragments being linked so that the gene is expressed.

Claims 2-15, which depend from claim 1, recite preferred *Bacillus* species, promoters, and selectable markers. 5 Independent claim 16 and claims 17-31 which depend therefrom are directed to a hybrid plasmid vector which includes the chimeric gene of claim 1. Claim 32 recites a bacterial strain. Independent claim 33 and claims 34-48 which depend therefrom recite a cyanobacterium which expresses the chimeric gene of claim 1. Claims 50-51 recite an insecticidal composition. Claim 52 recites a particular plasmid that appellants have deposited.

B. *Appellants' Disclosure*

In addition to describing the claimed invention in generic terms, appellants' specification discloses two particular species of *Bacillus* (*B. thuringiensis, B. sphaericus*) as sources of insecticidal protein; and nine genera of cyanobacteria (*Synechocystis, Anacystis, Synechococcus, Agmenellum, Aphanocapsa, Gloecapsa, Nostoc, Anabaena* and *Ffremyllia*) as useful hosts.
The working examples relevant to the claims on appeal detail the transformation of a

single strain of cyanobacteria, i.e., *Synechocystis* 6803. In one example, *Synechocystis* 6803 cells are transformed with a plasmid comprising (1) a gene encoding a particular insecticidal protein ("B.t. 8") from *Bacillus thuringiensis* var. *israelensis,* linked to (2) a particular promoter, the P $_L$promoter from the bacteriophage Lambda (a virus of *E. coli*). In another example, a different promoter, i.e., the *Synechocystis* 6803 promoter for the rubisco operon, is utilized instead of the Lambda P $_L$promoter.

C. *The Prior Art*

A total of eleven prior art references were cited and applied, in various combinations, against the claims on appeal.
The focus of Dzelzkalns, 6 the primary reference cited against all of the rejected claims, is to determine whether chloroplast promoter sequences can function in cyanobacteria. To that end Dzelzkalns discloses the expression in cyanobacteria of a chimeric gene comprising a chloroplast promoter sequence fused to a gene encoding the enzyme chloramphenicol acetyl transferase (CAT). 7 Importantly, Dzelzkalns teaches the use of the CAT gene as a "marker" gene; this use of antibiotic resistance-conferring genes for selection purposes is a common technique in genetic engineering.

Sekar I, 8 Sekar II, 9 and Ganesan 10 collectively disclose expression of genes encoding certain *Bacillus* insecticidal proteins in the bacterial hosts *B. megaterium, B. subtilis* and *E. coli.*
Friedberg 11 discloses the transformation of the cyanobacterium *Anacystis nidulans* R2 by a plasmid vector comprising the O $_L$P $_L$operator-promoter region and a temperature-sensitive repressor gene of the bacteriophage Lambda. While the cyanobacteria are attractive organisms for the cloning of genes involved in photosynthesis, Friedberg states, problems may still be encountered such as suboptimal expression of the cloned gene, detrimental effects on cell growth of overexpressed, highly hydrophobic proteins, and rapid turnover of some gene products. To address these problems, Friedberg teaches the use of the disclosed Lambda regulatory signals in plasmid vehicles which, it states, have "considerable potential for use as vectors the expression of which can be controlled in *Anacystis* ...."
Miller 12 compares the initiation specificities *in vitro* of DNA-dependent RNA polymerases 13 purified from two different species of cyanobacteria (*Fremyella diplosiphon* and *Anacystis nidulans*), as well as from *E. coli.*
Nierzwicki-Bauer 14 identifies in the cyanobacterium *Anabaena* 7120 the start site for transcription of the gene encoding *rbc* L, the large subunit of the enzyme ribulose-1, 5-bisphosphate carboxylase. It reports that the nucleotide sequence 14-8 base pairs preceding the transcription start site "resembles a good *Escherichia coli* promoter," but that the sequence 35 base pairs before the start site does not.
Chauvat 15 discloses host-vector systems for gene cloning in the cyanobacterium *Synechocystis* 6803, in which the antibiotic resistance-conferring *neo* gene is utilized as a selectable marker.
Reiss 16 studies expression in *E. coli* of various proteins formed by fusion of certain

foreign DNA sequences with the *neo* gene.
Kolowsky 17 discloses chimeric plasmids designed for transformation of the cyanobacterium *Synechococcus* R2, comprising an antibiotic-resistant gene linked to chromosomal DNA from the *Synechococcus* cyanobacterium.
Barnes, United States Patent No. 4,695,455, is directed to the treatment with stabilizing chemical reagents of pesticides produced by expression of heterologous genes (such as those encoding *Bacillus* proteins) in host microbial cells such as *Pseudomonas* bacteria. The host cells are killed by this treatment, but the resulting pesticidal compositions exhibit prolonged toxic activity when exposed to the environment of target pests.

D. *The Grounds of Rejection*

1. The § 103 Rejections

Claims 1-6, 16-21, 33-38, 47-48 and 52 (which include all independent claims in the application) were rejected as unpatentable under 35 USC 103 based upon Dzelzkalns in view of Sekar I or Sekar II and Ganesan. The examiner stated that Dzelzkalns discloses a chimeric gene capable of being highly expressed in a cyanobacterium, said gene comprising a promoter region effective for expression in a cyanobacterium operably linked to a structural gene encoding CAT. The examiner acknowledged that the chimeric gene and transformed host of Dzelzkalns differ from the claimed invention in that the former's structural gene encodes CAT rather than insecticidally active protein. However, the examiner pointed out, Sekar I, Sekar II, and Ganesan teach genes encoding insecticidally active proteins produced by *Bacillus,* and the advantages of expressing such genes in heterologous 18 hosts to obtain larger quantities of the protein. The examiner contended that it would have been obvious to one of ordinary skill in the art to substitute the *Bacillus* genes taught by Sekar I, Sekar II, and Ganesan for the CAT gene in the vectors of Dzelzkalns in order to obtain high level expression of the *Bacillus* genes in the transformed cyanobacteria. The examiner further contended that it would have been obvious to use cyanobacteria as heterologous hosts for expression of the claimed genes due to the ability of cyanobacteria to serve as transformed hosts for the

expression of heterologous genes. In the absence of evidence to the contrary, the examiner contended, the invention as a whole was prima facie obvious.
Additional rejections were entered against various groups of dependent claims which we need not address here. All additional rejections were made in view of Dzelzkalns in combination with Sekar I, Sekar II, and Ganesan, and further in view of other references discussed in Part C above.
The Board affirmed the § 103 rejections, basically adopting the examiner's Answer as its opinion while adding a few comments. The legal conclusion of obviousness does not require absolute certainty, the Board added, but only a reasonable expectation of success, citing *In re O'Farrell,* 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). In view of the disclosures of the prior art, the Board concluded, one of ordinary skill in the art would have been motivated by a reasonable expectation of success to make the substitution suggested by the examiner.

2. The § 112 Rejection

The examiner also rejected claims 1-48 and 50-51 under 35 USC 112, first paragraph, on the ground that the disclosure was enabling only for claims limited in accordance with the specification as filed. Citing *Manual of Patent Examining Procedure* (MPEP) provisions 706.03(n) 19 and (z) 20 as support, the examiner took the position that undue experimentation would be required of the art worker to practice the claimed invention, in view of the unpredictability in the art, the breadth of the claims, the limited number of working examples and the limited guidance provided in the specification. With respect to unpredictability, the examiner stated that

he cyanobacteria comprise a large and diverse group of photosynthetic bacteria including large numbers of species in some 150 different genera including *Synechocystis, Anacystis, Synechococcus, Agmenellum, Nostoc, Anabaena,* etc. The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability regarding heterologous gene expression in this large, diverse and relatively poorly studied group of procaryotes is high....

The Board affirmed, noting that "the limited guidance in the specification, considered in light of the relatively high degree of unpredictability in this particular art, would not have enabled one having ordinary skill in the art to practice the broad scope of the claimed invention without undue experimentation. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970)."

OPINION

A. *Obviousness*

We first address whether the PTO erred in rejecting the claims on appeal as prima facie obvious within the meaning of 35 USC 103. Obviousness is a legal question which this court independently reviews, though based upon underlying factual findings which we review under the clearly erroneous standard. *In re Woodruff,* 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990).

[1] Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia,* consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *See In re Dow Chemical Co.,* 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Id.*

[2] We agree with appellants that the PTO has not established the prima facie obviousness of the claimed subject matter. The prior art simply does not disclose or suggest the expression in cyanobacteria of a chimeric gene encoding an insecticidally

active protein, or convey to those of ordinary skill a reasonable expectation of success in doing so. More particularly, there is no suggestion in Dzelzkalns, the primary reference cited against all claims, of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes. The expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious the expression of unrelated genes in cyanobacteria for unrelated purposes.

The PTO argues that the substitution of insecticidal *Bacillus* genes for CAT marker genes in cyanobacteria is suggested by the secondary references Sekar I, Sekar II, and Ganesan, which collectively disclose expression of genes encoding *Bacillus* insecticidal proteins in two species of host *Bacillus* bacteria (*B. megaterium* and *B. subtilis*) as well as in the bacterium *E. coli*. While these references disclose expression of *Bacillus* genes encoding insecticidal proteins in certain transformed *bacterial* hosts, nowhere do these references disclose or suggest expression of such genes in transformed *cyanobacterial* hosts.

To remedy this deficiency, the PTO emphasizes similarity between bacteria and cyanobacteria, namely, that these are both procaryotic organisms, and argues that this fact would suggest to those of ordinary skill the use of cyanobacteria as hosts for expression of the claimed chimeric genes. While it is true that bacteria and cyanobacteria are now both classified as procaryotes, that fact alone is not sufficient to motivate the art worker as the PTO contends. As the PTO concedes, cyanobacteria and bacteria are not identical; they are classified as two separate divisions of the kingdom Procaryotae. 21 Moreover, it is only in recent years that the biology of cyanobacteria has been clarified, as evidenced by references in the prior art to "blue-green algae." Such evidence of recent uncertainty regarding the biology of cyanobacteria tends to rebut, rather than support, the PTO's position that one would consider the cyanobacteria effectively interchangeable with bacteria as hosts for expression of the claimed gene.

At oral argument the PTO referred to additional secondary references, not cited against any independent claim (i.e., Friedberg, Miller, and Nierzwicki-Bauer), which it contended disclose certain amino acid sequence homology between bacteria and cyanobacteria. The PTO argued that such homology is a further suggestion to one of ordinary skill to attempt the claimed invention. We disagree. As with the Dzelzkalns, Sekar I, Sekar II, and Ganesan references discussed above, none of these additional references disclose or suggest that cyanobacteria could serve as hosts for expression of genes encoding *Bacillus* insecticidal proteins. In fact, these additional references suggest as much about *differences* between cyanobacteria and bacteria as they do about similarities. For example, Nierzwicki-Bauer reports that a certain nucleotide sequence (i.e., the -10 consensus sequence) in a particular cyanobacterium resembles an *E. coli* promoter, but that another nearby nucleotide sequence (the -35 region) does not. While Miller speaks of certain promoters of the bacteriophage Lambda that are recognized by both cyanobacterial and *E. coli* RNA polymerases, it also discloses that these promoters exhibited differing strengths when exposed to the different polymerases. Differing sensitivities of the respective polymerases to an inhibitor are also disclosed, suggesting differences in the structures of the initiation complexes.

The PTO asks us to agree that the prior art would lead those of ordinary skill to conclude that cyanobacteria are attractive hosts for expression of any and all heterologous genes.

Again, we can not. The relevant prior art does indicate that cyanobacteria are attractive hosts for expression of both native and heterologous *genes involved in photosynthesis* (not surprisingly, for the capability of undergoing oxygenic photosynthesis is what makes the cyanobacteria unique among procaryotes). However, these references do not suggest that cyanobacteria would be equally attractive hosts for expression of *unrelated* heterologous genes, such as the claimed genes encoding *Bacillus* insecticidal proteins. In *O'Farrell,* this court affirmed an obviousness rejection of a claim to a method for

producing a "predetermined protein in a stable form" in a transformed bacterial host. 853 F.2d at 895, 7 USPQ2d at 1674. The cited references included a prior art publication (the Polisky reference) whose three authors included two of the three coinventor-appellants. The main difference between the prior art and the claim at issue was that in Polisky, the heterologous gene was a gene for ribosomal RNA, while the claimed invention substituted a gene coding for a predetermined protein. *Id.* at 901, 7 USPQ2d at 1679. Although, as the appellants therein pointed out, the ribosomal RNA gene is not normally translated into protein, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein, and further predicted that if a gene coding for a protein were to be substituted, extensive translation might result. *Id.* We thus affirmed, explaining that

> the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the [claimed] method could be used to make proteins.
>
> ....
>
> ... Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.

Id. at 901-02, 7 USPQ2d at 1679-80.

In contrast with the situation in *O'Farrell,* the prior art in this case offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art. Moreover, the "reasonable expectation of success" that was present in *O'Farrell* is not present here. Accordingly, we reverse the § 103 rejections.

B. *Enablement*

[3] The first paragraph of 35 USC 112 requires, *inter alia,* that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation." *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is "undue." *Id.* at 736-37, 8 USPQ2d at 1404. Enablement, like obviousness, is a question of law which we independently review, although based upon underlying factual findings which we review for clear error. *See id.* at 735, 8 USPQ2d at 1402.

In response to the § 112 rejection, appellants assert that their invention is "pioneering,"

and that this should entitle them to claims of broad scope. Narrower claims would provide no real protection, appellants argue, because the level of skill in this art is so high, art workers could easily avoid the claims. Given the disclosure in their specification, appellants contend that any skilled microbiologist could construct vectors and transform many different cyanobacteria, using a variety of promoters and *Bacillus* DNA, and could easily determine whether or not the active *Bacillus* protein was successfully expressed by the cyanobacteria.

The PTO made no finding on whether the claimed invention is indeed "pioneering," and we need not address the issue here. With the exception of claims 47 and 48, the claims rejected under § 112 are not limited to any particular genus or species of cyanobacteria. The PTO's position is that the cyanobacteria are a diverse and relatively poorly studied group of organisms, comprising some 150 different genera, and that heterologous gene expression in cyanobacteria is "unpredictable." Appellants have not effectively disputed these assertions. Moreover, we note that only one particular species of cyanobacteria is employed in the working examples of appellants' specification, and only nine genera of cyanobacteria are mentioned in the entire document.

[4] Taking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of particular cyanobacterial genera operative in the claimed invention, we are not persuaded that the PTO erred in rejecting claims 1-46 and 50-51 under § 112, first paragraph. There is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria. *See In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification).

22 Accordingly, we affirm the § 112 rejection as to those claims.

In so doing we do *not* imply that patent applicants in art areas currently denominated as "unpredictable" must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt,* 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, 23 to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element. *See Fisher,* 427 F.2d at 839, 166 USPQ at 24. In this case, we agree with the PTO that appellants' limited disclosure does not enable one of ordinary skill to make and use the invention as now recited in claims 1-46 and 50-51 without undue

experimentation.
Remaining dependent claim 47 recites a cyanobacterium which expresses the chimeric gene of claim 1, wherein the cyanobacterium is selected from among the genera *Anacystis* and *Synechocystis*. Claim 48, which depend from claim 47, is limited to the cyanobacterium *Synechocystis* 6803. The PTO did not separately address these claims, nor indicate why they should be treated in the same manner as the claims encompassing all types of cyanobacteria. Although these claims are not limited to expression of genes encoding particular *Bacillus* proteins, we note what appears to be an extensive understanding in the prior art of the numerous *Bacillus* proteins having toxicity to various insects. The rejection of claims 47-48 under § 112 will not be sustained.

CONCLUSION

The rejection of claims 1-48 and 50-52 under 35 USC 103 is *reversed*. The rejection of claims 1-46 and 50-51 under 35 USC 112, first paragraph, is *affirmed* and the rejection of claims 47 and 48 thereunder is *reversed*.
AFFIRMED-IN-PART, REVERSED-IN-PART

Footnotes

Footnote 1. Basic vocabulary and techniques for gene cloning and expression have been described in *In re O'Farrell*, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988), and are not repeated here.
Footnote 2. All living cells can be classified into one of two broad groups, procaryotes and eucaryotes. The procaryotes comprise organisms formed of cells that do not have a distinct nucleus; their DNA floats throughout the cellular cytoplasm. In contrast, the cells of eucaryotic organisms such as man, other animals, plants, protozoa, algae and yeast have a distinct nucleus wherein their DNA resides.
Footnote 3. "Transformed" cyanobacteria are those that have successfully taken up the foreign *Bacillus* DNA such that the DNA information has become a permanent part of the host cyanobacteria, to be replicated as new cyanobacteria are generated.
Footnote 4. "Expression" of a gene refers to the production of the protein which the gene encodes; more specifically, it is the process of transferring information from a gene (which consists of DNA) via messenger RNA to ribosomes where a specific protein is made.
Footnote 5. In the context of the claimed invention, "selectable markers" or "marker genes" refer to antibiotic-resistance conferring DNA fragments, attached to the gene being expressed, which facilitate the selection of successfully transformed cyanobacteria.
Footnote 6. *Nucleic Acids Res.* 8917 (1984).
Footnote 7. Chloramphenicol is an antibiotic; CAT is an enzyme which destroys chloramphenicol and thus imparts resistance thereto.
Footnote 8. *Biochem. and Biophys. Res. Comm.* 748 (1986).
Footnote 9. *Gene* 151 (1985).
Footnote 10. *Mol. Gen. Genet.* 181 (1983).
Footnote 11. *Mol. Gen. Genet.* 505 (1986).
Footnote 12. *J. Bacteriology* 246 (1979).

Footnote 13. RNA polymerase, the enzyme responsible for making RNA from DNA, binds at specific nucleotide sequences (promoters) in front of genes in DNA, and then moves through the gene making an RNA molecule that includes the information contained in the gene. Initiation specificity is the ability of the RNA polymerase to initiate this process specifically at a site(s) on the DNA template.
Footnote 14. *Proc. Natl. Acad. Sci. USA* 5961 (1984).
Footnote 15. *Mol. Gen. Genet.* 185 (1986).
Footnote 16. *Gene* 211 (1984).
Footnote 17. *Gene* 289 (1984).
Footnote 18. Denotes different species or organism.
Footnote 19. MPEP 706.03(n), "Correspondence of Claim and Disclosure," provides in part:
In chemical cases, a claim may be so broad as to not be supported by [the] disclosure, in which case it is rejected as unwarranted by the disclosure....
Footnote 20. MPEP 796.03(z), "Undue Breadth," provides in part:
n applications directed to intentions in arts were the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Sol,* 1938 C.D. 723; 497 O.G. 546. This is because in arts such as chemistry it is not obvious from the disclosure of one species, what other species will work. *In re Dreshfield,* 1940 C.D. 351; 518 O.G. 255 gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." ...
Footnote 21. *Stedman's Medical Dictionary* 1139 (24th ed. 1982) (definition of "Procaryotae"). Procaryotic organisms are commonly classified according to the following taxonomic hierarchy: Kingdom; Division; Class; Order; Family; Genus; Species. 3 *Bergey's Manual of Systematic Bacteriology* 1601 (1989).
Footnote 22. The enablement rejection in this case was not based upon a post-filing date state of the art, as in *In re Hogan,* 559 F.2d 595, 605-07, 194 USPQ 527, 536-38 (CCPA 1977). *See also United States Steel Corp. v. Phillips Petroleum Co.,* 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989) (citing *Hogan*); *Hormone Research Found., Inc. v. Genentech, Inc.,* 904 F.2d 1558, 1568-69, 15 USPQ2d 1039, 1047-48 (Fed. Cir. 1990) (directing district court, on remand, to consider effect of *Hogan* and *United States Steel* on the enablement analysis of *Fisher*), *cert. dismissed,* — U.S. —, 111 S. Ct. 1434 (1991). We therefore do not consider the effect of *Hogan* and its progeny on *Fisher* 's analysis of when an inventor should be allowed to "dominate the future patentable inventions of others." *Fisher,* 427 F.2d at 839, 166 USPQ at 24.
Footnote 23. The first paragraph of § 112 requires nothing more than *objective* enablement. *In re Marzocchi,* 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is irrelevant. *Id.*

Dissenting Opinion Text

Dissent By:

Mayer, J., dissenting.

An appeal is not a second opportunity to try a case or prosecute a patent application, and we should not allow parties to "undertake to retry the entire case on appeal." *Perini America, Inc. v. Paper Converting Machine Co.*, 832 F.2d 581, 584, 4 USPQ2d 1621, 1624 (Fed. Cir. 1987); *Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 877, 229 USPQ 668, 671 (Fed. Cir. 1986). But that is precisely what the court has permitted here. The PTO conducted a thorough examination of the prior art surrounding this patent application and concluded the claims would have been obvious. The board's decision based on the examiner's answer which comprehensively explains the rejection is persuasive and shows how the evidence supports the legal conclusion that the claims would have been obvious. Yet, the court ignores all this and conducts its own examination, if you will, as though the examiner and board did not exist. Even if thought this opinion were more persuasive than the board's, I could not join it because it misperceives the role of the court.

The scope and content of the prior art, the similarity between the prior art and the claims, the level of ordinary skill in the art, and what the prior art teaches are all questions of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *Jurgens v. McKasy*, 927 F.2d 1552, 1560, 18 USPQ2d 1031, 1037 (Fed. Cir. 1991). And "[w]here there are two permissible views of

the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985). The mere denomination of obviousness as a question of law does not give the court license to decide the factual matters afresh and ignore the requirement that they be respected unless clearly erroneous. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990); *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir. 1990). There may be more than one way to look at the prior art, but on this record we are bound by the PTO's interpretation of the evidence because it is not clearly erroneous and its conclusion is unassailable. I would affirm on that basis.

- End of Case -

Intellectual Property Library ISSN 1526-8535

Intellectual Property Library ISSN 1526-8535

Serial No. 09/438,206
Group No. 1617
Confirmation No. 9018

FULL TEXT OF CASES (USPQ FIRST SERIES)

In re DINH-NGUYEN AND STENHAGEN

(CCPA)
181 USPQ 46
Decided Feb. 28, 1974
No. 9134
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Pleading and practice in Patent Office — Rejections (§ 54.7)

Specification — Sufficiency of disclosure (§ 62.7)

Assertion by Patent Office that enabling disclosure is not commensurate in scope with protection sought must be supported by evidence or reasoning substantiating doubts so expressed.

2. Claims — Process (§ 20.80)

Specification — Sufficiency of disclosure (§ 62.7)

It being implicit in claims that conditions of process have not been met unless catalyst is present and active as a catalyst, it is an unnecessary limitation to require recitation in claims of specific proportions employed in examples to insure that activity; disclosure in specification sufficient to enable practice of invention by one skilled in the art, taking into consideration obvious modifications of reactant ratios of specific examples, is all that is required; it is not a function of claims to specifically exclude either possible inoperative substances or ineffective reactant proportions.

Particular patents—Organic Compounds

Dinh-Nguyen and Stenhagen, Method of Deuterating Organic Compounds, claims 2, 3, and 11 to 16 of application allowed.

Case History and Disposition:

Appeal from Board of Appeals of the Patent Office.

Application for patent of Nguyen Dinh-Nguyen and Einar August Stenhagen, Serial No. 768,950, filed Sept. 16, 1968; Patent Office Group 120. From decision rejecting claims 2, 3, and 11 to 16, applicants appeal. Reversed.

Attorneys:

ANTHONY M. LORUSSO, Washington, D. C., and KENWAY, JENNEY & HILDRETH, Boston, Mass., for appellants.

JOSEPH F. NAKAMURA (HENRY W. TARRING, II, of counsel) for Commissioner of Patents.

Judge:

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE, and MILLER, Associate Judges.

Opinion Text

Opinion By:

MARKEY, Chief Judge.

This appeal is from the decision of the Board of Appeals, affirming the rejection under 35 U.S.C. 112 of claims 2, 3 and 11 to 16 of appellants' application, serial No. 768,950 filed September 16, 1968, for "Method of Deuterating Organic Compounds." [1] We reverse.

The Invention

The application is directed to the improvement of the process of exchanging the heavy isotope deuterium for hydrogen in organic compounds by the use of deuterium peroxide as a promoter. It is stated in the specification that the presence of this promoter permits the replacement of hydrogen in a "great many organic compounds including compounds of high molecular weight" whereas the earlier methods were only effective with compounds of low molecular weight.

All of the claims are in Jepson form, claim 11 reciting the claimed process in its

broadest scope:

> 11. In the method of deuterating an organic compound containing hydrogen atoms replaceable by deuterium wherein said compound is reacted with heavy water as a deuterium source in the presence of alkali metal deuteroxide and a deuterium reduced Adams catalyst (PtO $_2$H $_2$O) the improvement which consists in carrying out the deuterating reaction in the present [sic] of deuterium peroxide.

Claim 12 restricts the alkali metal deuteroxide to the sodium species, with further dependent claims 2 and 3 defining specific methods for producing the catalyst, promoter and deuteroxide. Remaining dependent claims 13-16 limit the "deuteratable organic compound" of claim 11 to "a hydrocarbon," "an alcohol," "a keton [sic]," or "a fatty acid," respectively.

The Rejection

The examiner's rejection under 35 U.S.C. 112 was based on the conclusion that the specification failed to "effectively support the scope" of the claims. It was his position that the claims encompassed the use of a broad range of organic compounds in the deuteration process, many of which might "properly be expected to undergo interfering reactions." The known reactivity of hydrogen peroxide with many organic compounds was cited as support for the holding of inadequate disclosure of suitable operating conditions when similar oxidation reactions might be expected due to the presence of its counterpart deuterium peroxide.

The board agreed with the examiner, stating:

> None of the appealed claims precludes as a starting material compounds containing groups reactive with deuterium peroxide. The specific examples are devoid of representatives thereof, and the specification, therefore, does not demonstrate how the claimed process would produce an improvement where the stated reactants containing reactive groups are employed. We might particularly note that olefinic, and particularly diolefinic, compounds, which may be hydrocarbons, alcohols, ketones or fatty acids as indicated in the dependent claims, react vigorously with hydrogen peroxide to either split, epoxidize or produce other products, dependent upon reaction conditions. Similar interfering reaction with deuterium peroxide is to be expected and the resulting process is not the argued improvement of an old process since the same product is not obtained as is provided where the oxidizing agent is absent and there is no evidence that the process itself is in any way improved.

The board also concluded that the deuterium peroxide in sufficient quantity might be expected to oxidize the Adams catalyst and thus preclude "the desired results."

Appellants maintain that their invention lies in the specific improvement of an old process by the incorporation of the promoter deuterium peroxide. Jepson claims have been used to pinpoint this improvement, the preamble simply setting forth the known deuteration process. Furthermore, it is argued that all the requirements of 35 U.S.C. 112

have been complied with insofar as the deuteration is concerned, which is all that is necessary. Disclosure of means for dealing with possible interfering reactions is said not to fall within the required teaching of how to make and use the claimed invention.

The solicitor, on the other hand, contends the board properly held that the enabling disclosure is "not commensurate in scope with the claim terminology" in that the possibility of undesirable side reactions with certain compounds has not been dealt with. The reasons given by the examiner and board, in addition to the apparent concession by appellants that side reactions might occur, are alleged to establish "at least a strong probability that the invention as broadly claimed encompasses significant areas wherein the process would be inoperative, or at the least, inadequately disclosed."

Opinion

Although the rejection has not been stated in terms of any particular requirement of 35 U.S.C. 112, we consider the issue to be restricted to the enabling disclosure requirement of the first paragraph. No real challenge has been made to the claims as not setting forth that which appellants regard as their invention, only the adequacy of support therefor.

Accordingly, the touchstone is that which is claimed. Deuteration by the general method recited in the preamble of appellants' claims is a known process. Although, as acknowledged in appellants' specification, the applicability of that process was limited to certain classes of organic compounds, the basic procedure was a part of the prior art. Appellants' contribution lies in extending the effectiveness of the process by the addition of a particular promoter. The process may still be characterized as "deuterating an organic compound containing hydrogen atoms replaceable by deuteration," even though the scope of deuterable compounds has been widened. Thus the accompanying disclosure in the specification need only be sufficient to enable those skilled in the art to achieve deuteration of potentially deuterable compounds in the presence of deuterium peroxide.

Looking to appellants' specification, we find not only a general discussion of the procedure to be followed but also three specific examples outlining the preparation of the Adams catalyst, the alkali catalyst, and the promoter as well as the exchange reaction with stearic acid, camphor, and anthracene. All the "deuteratable" compounds are of high molecular weight and all are deuterated by appellants' improved process. The obvious general applicability of the procedure so demonstrated fully satisfies the enabling disclosure requirement of 35 U.S.C. 112.

[1] Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. In re Bowen, 181 USPQ 48 , Patent Appeal No. 9135, decided concurrently herewith; In re Gardner, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); In re Marzocchi, 58 CCPA 1069, 439 F.2d 220, 169 USPQ 367 (1971). Here the challenges enumerate possible interfering reactions but, as pointed out by appellants, there has been no challenge whatever to appellants' repeated assertions that the starting materials containing the so-called "reactive groups" *are* deuterated. The hypothesized oxidation or even destruction of the original compounds per se, by splitting or other mechanism, cannot be considered an indication of the inoperability of the replacement reaction. The only valid assumption is that the form of the final deuterated product might differ from that of the starting material. Such a change is not inconsistent

with claim language, which merely calls for

"deuterating an organic compound * * *" and creates no requirement that said compound remain otherwise unaffected during the course of the reaction. The "improvement" relates to the expanded effectiveness of the *deuteration* process, regardless of the possible birth or increase of side reactions due to the presence of the promoter. The enabling disclosure need only be of commensurate scope.

[2] Although the board also hypothesized that the peroxide might oxidize the Adams catalyst necessary for the deuteration into inactivity, we agree with appellants that it is implicit in the claims that the conditions of the process have not been met unless the catalyst is present and active as a catalyst. Requiring a recitation in the claims of the specific deuterium peroxide proportions employed in the examples to insure that activity would be an unnecessary limitation. Disclosure in the *specification* sufficient to enable practice of the invention by one skilled in the art, taking into consideration obvious modifications of the reactant ratios of specific examples, is all that is required. It is not a function of the *claims* to specifically exclude either possible inoperative substances or ineffective reactant proportions. In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

The decision of the board is *reversed.*

Footnotes

Footnote 1. An apparent continuation of serial No. 522,030, filed January 21, 1966.

- End of Case -

Intellectual Property Library ISSN 1526-8535

Serial No. 09/438,206
Group No. 1617
Confirmation No. 9018

Intellectual Property Library ISSN 1526-8535

FULL TEXT OF CASES (USPQ2D)
All Other Cases

In re Wright (CA FC) 27 USPQ2d 1510 In re Wright

U.S. Court of Appeals Federal Circuit
27 USPQ2d 1510

Decided July 20, 1993
No. 92-1437

Headnotes

PATENTS

1. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Judicial review -- Standard of review -- Patents (§ 410.4607.09)

Statutory requirement of enablement is question of law that is reviewed de novo on appeal, but any underlying facts found by Board of Patent Appeals and Interferences in rendering its enablement determination will be reviewed for clear error.

2. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Patent and Trademark Office, in rejecting claim under enablement requirement of 35 USC 112, bears initial burden of setting forth reasonable explanation of why scope of

protection provided by claim is not adequately enabled by specification's description of invention, and this burden includes providing sufficient reasons for doubting any assertions in specification as to scope of enablement; if PTO meets this burden, then burden shifts to applicant to provide suitable proofs indicating that specification is enabling.

3. Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Patent and Trademark Office set forth reasonable basis for its finding that scope of claims directed to producing live, non-pathogenic vaccines against pathogenic RNA viruses is not enabled by specification's general description, which contained only single working example directed to uniquely tailored in vitro method of producing particular recombinant virus vaccine, and applicant has failed to rebut this finding by demonstrating how skilled artisan in February 1983 would have been able, without undue experimentation, to carry out identification, isolation, cloning, recombination, and efficacy testing steps required to practice full scope of claims; applicant has also failed to show that claims, even if restricted to vaccines against avian tumor viruses, are enabled, since he has failed to establish that scientist at that time would have reasonably believed that applicant's success with particular strain of avian RNA virus could be extrapolated with reasonable expectation of success to other avian RNA viruses.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 06/914,620, filed by Stephen E. Wright. From board's decision sustaining examiner's rejection of claims, applicant appeals. Affirmed.

Attorneys:

Peter M. Peer, of Mallinckrodt & Mallinckrodt (Philip A. Mallinckrodt, with him on brief), Salt Lake City, Utah, for appellants.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor, with him on brief; Richard E. Schafer, John W. Dewhirst, Albin F. Drost, and Lee E. Barrett, of counsel), for PTO.

Judge:

Before Rich, Newman, and Rader, circuit judges.

Opinion Text

Opinion By:

Rich, J.

Dr. Stephen E. Wright appeals from the January 16, 1992 decision of the Board of Patent Appeals and Interferences (Board) of the United States Patent and Trademark Office (PTO) sustaining the Examiner's rejection of claims 1-23, 15-42, and 45-48 of application Serial No. 06/914,620 1 under 35 USC Section 112, first paragraph, as unsupported by an enabling disclosure.2 We affirm.

I. BACKGROUND

A. *The Invention*

The claims on appeal are directed to processes for producing live, non-pathogenic

vaccines against pathogenic RNA viruses (claims 1-10, 22-37, 40, 45, and 46), vaccines produced by these processes (claims 11, 12, 15-21, 38, and 39), and methods of using certain of these claimed vaccines to protect living organisms against RNA viruses (claims 41 and 42). Wright's specification provides a general description of these processes, vaccines, and methods of use, but only a single working example.

In this example, Wright describes the production of a recombinant vaccine which confers immunity in chickens against the RNA tumor virus known as Prague Avian Sarcoma Virus (PrASV), a member of the Rous Associated Virus (RAV) family. To produce this vaccine, Wright first identified the antigenic gene region of the genome of PrASV as being in the envelope A (*env* A) gene region of this virus, and then isolated and cloned a large quantity of this antigenic gene region. Following cloning, Wright introduced by transfection the cloned *env* A genes into C/O cells, a particular chicken embryo cell line. The C/O cells were then infected with the endogenous, non-oncogenic, O-type Rous Associated Virus (RAV-O) and incubated. Genetic recombination and viral replication occurred during incubation, resulting in an impure vaccine containing particles of the recombinant virus referred to as RAV-O Acn, or RAV-O-A. 3 Wright then purified this vaccine to obtain a vaccine containing only genetic recombinant RAV-Acn virus particles. The Examiner ultimately allowed claims 13, 14, 43, and 44, which are specific to the particular process and vaccine disclosed in this example.4

Wright seeks allowance, however, of claims which would provide, in varying degrees, a much broader scope of protection than the allowed claims. For example, independent process claim 1 reads:

A process for producing a live non-pathogenic vaccine for a pathogenic RNA virus, comprising the steps of identifying the antigenic and pathogenic gene regions of said

virus; performing gene alteration to produce a genome which codes for the antigenicity of the virus, but does not have its pathogenicity; and obtaining an expression of the gene. Dependent claims 2-10, 22-35, and 40 recite additional limitations to this process. Independent claims 36 and 45 and claims 37 and 46 dependent therefrom, respectively, are also directed to processes for producing vaccines.

Independent product claim 11 reads:

A live, non-pathogenic vaccine for a pathogenic RNA virus, comprising an immunologically effective amount of a viral antigenic, genomic expression having an antigenic determinant region of the RNA virus, but no pathogenic properties.

Dependent claims 15-21 recite additional limitations to this vaccine. Independent claims 38 and 47 and claims 39 and 48 dependent therefrom, respectively, are also directed to vaccines.

Dependent claims 41 and 42 recite methods of protecting living organisms against RNA viruses, which comprise introducing into a host an immunologically effective amount of the vaccine of claims 11 and 38, respectively.

B. *The Rejection*

The Examiner took the position in her Examiner's Answer that the claims presently on appeal are not supported by an enabling disclosure because one of ordinary skill in the art would have had to engage in undue experimentation in February of 1983 (the effective filing date of Wright's application) to practice the subject matter of these claims, given their breadth, the unpredictability in the art, and the limited guidance Wright provides in his application. The Examiner noted that many of Wright's claims read on vaccines against *all* pathogenic RNA viruses, even though RNA viruses are a very diverse and genetically complex group of

viruses which include, among others, acquired immunodeficiency syndrome (AIDS) viruses, leukemia viruses, and sarcoma viruses. The Examiner argued that Wright's single working example merely evidenced that Wright had obtained successfully a particular recombinant virus vaccine, and that this single success did not provide "sufficient likelihood" that other recombinant RNA viruses could be constructed without undue experimentation, or if they were constructed, that they would be useful in the design of like viral vaccines. The Examiner noted the inability of the scientific community to develop an efficacious AIDS virus vaccine for humans despite devoting a considerable amount of time and money to do so.

The Examiner further argued that, even though retroviruses as a class may exhibit similar gene order and possess envelope proteins, this alone does not support a general conclusion that all RNA virus envelope proteins will confer protection against the corresponding virus. The Examiner asserted that this held true even among avian RNA tumor viruses. At page 11 of her Answer, the Examiner stated that "one envelope gene's immunogenicity cannot be extrapolated to another envelope gene. The efficacy of each should be ascertained individually."

To support the foregoing, the Examiner relied upon an article by Thomas J. Matthews et al., *Prospects for Development of a Vaccine Against HIV* , in Human Retroviruses, Cancer, and AIDS: Approaches to Prevention and Therapy 313-25 (1988). This article

indicates that AIDS retroviruses, which represent only a subset of all RNA viruses, were known even as late as 1988 to show great genetic diversity, including divergent virus envelopes. It further indicates that, although AIDS retroviruses elicited strong immune responses in goats and chimps in 1988, the resulting antibodies did not prevent retrovirus infectivity. Moreover, this article also recognizes at page 321 that, as of 1988, animal models for HIV infection and disease were likely to be imperfect, and therefore testing of primary vaccine candidates in man was necessary to determine safety, immunogenicity and efficacy.

Finally, the Examiner also argued that, irrespective of immunogenicity and vaccine considerations, the methods of identification, isolation, cloning, and recombination which Wright describes in his application in only a very general manner were not so developed in 1983 as to enable, without undue experimentation, the design and production of recombinant virus vaccines against any and all RNA viruses. The Examiner also asserted that the considerable amount of time and effort that it took Wright to construct the particular avian recombinant virus described in his single working example and to establish its efficacy as a vaccinating agent illustrates the amount of undue experimentation that would have been required in February of 1983 to practice Wright's invention, especially given that the efficacy of the developed virus could not be extrapolated with any certainty to other recombinant viruses at that time.

C. *The Board Decision*

In its January 16, 1992 decision, 5 the Board held that the Examiner did not err in questioning the enablement of the physiological activity required by the appealed claims, given the breadth of these claims and the fact that a vaccine must by definition provoke an immunoprotective response upon administration. The Board found that Wright had failed to establish that the general description of his invention set forth in his application was anything more, in February of 1983, than an invitation to experiment. The Board agreed with the Examiner that this general description does not set forth such sufficient detailed guidance that one of ordinary skill in the art would have had any reasonable expectation of success in constructing other vaccines against other RNA viruses. The Board additionally noted that the Examiner only allowed the claims limited to Wright's single working example after Wright submitted *in vivo* evidence of the efficacy of this vaccine.

The Board further held that the record did not support Wright's arguments that this single working example enables some of his dependent claims which are closer in scope to the allowed claims than to independent claims 1 and 11. The Board found that, even if Wright was correct in stating that it was generally known that an "immune response" is assured by use of an antigenic envelope protein, the record did not establish that such an "immune response" would have been an immunoprotective one, or moreover, that one skilled in this art would have expected such a result in February of 1983. The Board relied upon the Matthews et al. article as evidencing that "the mere use of an envelope protein gene in the present invention is not seen to necessarily result in the obtention of successful vaccines throughout the scope of

even these more limited claims." Bd. Dec. at 6.

As to Wright's request that the Board consider several declarations and exhibits of record, the Board stated that it found no reason to consider this evidence with any particularity since Wright had failed to advance any specific arguments based on this evidence or to explain its relevance.

II. DISCUSSION A.

[1] The first paragraph of 35 USC Section 112 requires that the specification of a patent contain a written description of the claimed invention and the manner and process of making and using that invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to which that invention pertains, or with which it is most nearly connected, to make and use that invention. As a statutory requirement, enablement is a question of law that we review de novo; however, we review for clear error any underlying facts found by the Board in rendering its enablement determination. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *In re Wands*, 858 F.2d 731, 735, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." *Vaeck*, 947 F.2d at 495, 20 USPQ2d at 1444; *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404; *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of section 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification). Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

[2] When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling. *Marzocchi*, 439 F.2d at 223-24, 169 USPQ at 369-70.

B.

In the present case, the PTO set forth a reasonable basis for finding that the scope of the appealed claims is not enabled by the general description and the single working example in the specification. Consequently, the burden shifted to Wright to present persuasive arguments, supported by suitable proofs where necessary, that the appealed claims are truly enabled. Wright failed to meet this burden.

Both the Examiner and the Board correctly pointed out that Wright's appealed claims are directed to vaccines, and methods of making and using these vaccines, which must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough. 6 Both also correctly pointed out that Wright attempts to claim in many of the appealed claims *any and all* live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in *any* animal toward

any RNA virus. In addition, both properly stressed that many of the appealed claims encompass vaccines against AIDS viruses and that, because of the high degree of genetic, antigenic variations in such viruses, no one has yet, years after his invention, developed a generally successful AIDS virus vaccine.
The Matthews et al. article, published approximately 5 years after the effective filing date of Wright's application, adequately supports the Examiner's and the Board's position that, in February of 1983, the physiological activity of RNA viruses was sufficiently unpredictable that Wright's success in developing his specific avian recombinant virus vaccine would not have led one of ordinary skill in the art to believe reasonably

that all living organisms could be immunized against infection by any pathogenic RNA virus by inoculating them with a live virus containing the antigenic code but not the pathogenic code of the RNA virus. The general description and the single example in Wright's specification, directed to a uniquely tailored *in vitro* method of producing in chicken C/O cells a vaccine against the PrASV avian tumor virus containing live RAV-Acn virus particles, did nothing more in February of 1983 than invite experimentation to determine whether other vaccines having *in vivo* immunoprotective activity could be constructed for other RNA viruses.
Wright argues that he has constructed successfully an *env* C recombinant vaccine according to the present invention and that certain recombinant AIDS virus vaccines carrying SIV (simian immunodeficiency virus) and HIV (human immunodeficiency virus) envelope genes have been produced which confer protective immunity in the animal models where they have been tested, 7 and that these developments illustrate that the art is not so unpredictable as to require undue experimentation. However, all of these developments occurred after the effective filing date of Wright's application and are of no significance regarding what one skilled in the art believed as of that date. 8 Furthermore, the fact that a few vaccines have been developed since the filing of Wright's application certainly does not by itself rebut the PTO's assertions regarding undue experimentation. Moreover, whether a few AIDS virus vaccines have been developed which confer immunity in some animal models is not the issue. The Examiner made reference to the difficulty that the scientific community is having in developing generally successful AIDS virus vaccines merely to illustrate that the art is not even today as predictable as Wright has suggested that it was back in 1983.
Wright also argues that several affidavits of record, namely, an October 22, 1984 declaration by Wright, an October 23, 1984 affidavit by O'Neill, and October 28, 1988 affidavits by Bennett and Burnett, successfully rebut the Board's and the Examiner's assertions regarding undue experimentation. However, Wright did not set forth in his brief to the Board any specific arguments regarding these affidavits, as required by 37 CFR 1.192(a), and therefore we are not required to address the arguments that Wright presents in this appeal regarding these affidavits. *Chester v. Miller* , 906 F.2d 1574, 1578 n.6, 15 USPQ2d 1333, 1337 n.6 (Fed. Cir. 1990); *In re Wiseman,* 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979).
[3] Nevertheless, we note that each of these affidavits fails in its purpose because each merely contains unsupported conclusory statements as to the ultimate legal question. 9

See In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991);

In re Brandstadter, 484 F.2d 1395, 1405-06, 179 USPQ 286, 293-94 (CCPA 1973). Furthermore, Burnett and Bennett do not even indicate in their affidavits that they actually reviewed the specification of Wright's application. In addition, although Wright states in his declaration that the individual steps making up his claimed process were "well within the skill of the art" at the time that he filed his application and makes reference to a list of publications that he contends supports this conclusory statement, a list which Wright also makes reference to in his arguments to this court, Wright fails to point out with any particularity in this declaration, or in his arguments to this court, how the listed documents evidence that a skilled artisan in February of 1983 would have been able to carry out, without undue experimentation, the identification, isolation, cloning, recombination, and efficacy testing steps required to practice the full scope of the appealed claims.

C.

Wright further argues that, even if those claims which provide a broad scope of protection are not enabled, this is not the case as to those claims restricted to vaccines against avian tumor viruses. Wright maintains that there is no doubt that it was known in 1983 that the technique of producing a live vaccine proven effective for one particular strain of avian RNA viruses would be effective as to other strains of avian RNA viruses. Wright argues that the scientific literature supports the position that the art was predictable at least with respect to avian RNA viruses, because gene function and order are similar among all avian RNA viruses.

We are not persuaded. Wright has failed to establish by evidence or arguments that, in February of 1983, a skilled scientist would have believed reasonably that Wright's success with a particular strain of an avian RNA virus could be extrapolated with a reasonable expectation of success to other avian RNA viruses. Indeed, Wright has failed to point out with any particularity the scientific literature existing in February of 1983 that supports his position. Furthermore, Wright's May 17, 1989 declaration indicates that Wright himself believed during the relevant time period that *in vivo* testing was necessary to determine the efficacy of vaccines. In this declaration, Wright stated in pertinent part:

Preparation of a patent application following conception of the invention awaited such time as there was a reasonable expectation that the results of innoculation [sic] would be successful. *This became apparent only by reason of survival of the chickens that had been innoculated* [sic].

Wright now argues that all he meant by the foregoing was that *in vivo* efficacy testing was necessary for the first avian RNA viruses vaccine that he developed in order to prove his hypothesis. Wright asserts that, once his hypothesis had been proven, a skilled artisan would have expected that similar *in vivo* results could be obtained for vaccines developed for other avian retroviruses. However, a paper that Wright co-authored with David Bennett, titled "Avian Retroviral Recombinant Expressing Foreign Envelope Delays Tumor Formation of ASV-A-Induced Sarcoma," which was attached to a

declaration by Wright dated November 19, 1985, suggests that, even as late as 1985, the genetic diversity existing among chickens alone required efficacy testing even among the members of this narrow group. 10 Accordingly, we see no error in the Board's finding that one skilled in the art would not have believed as early as February of 1983 that the success of Wright's one example could be extrapolated with a reasonable expectation of success to all avian RNA viruses.

D.

Finally, Wright argues that each of the appealed claims should be considered independently to determine whether it satisfies the enablement requirement of section 112. This we have done. Wright's arguments to this court, however, are directed almost entirely to why he believes that the specification of his application enables the appealed claims as a whole or at least those claims limited to avian RNA viruses. Although Wright does refer in passing to each of the appealed claims, he does little more than recite the particular limitations recited in these claims, failing to point out how the enablement requirement is satisfied as to each of these claims independently. Consequently, Wright has failed to provide us with any justification for finding that the Board erred in sustaining the Examiner's rejection, even with respect to some of the more limited claims.

CONCLUSION

For the foregoing reasons, the decision of the Board is affirmed.
AFFIRMED

Footnotes

Footnote 1. Application Serial No. 06/914,620, filed on October 2, 1986, is a continuation of Serial No. 06/469,985, filed February 25, 1983, now abandoned.
Footnote 2. In an April 12, 1992 reconsideration decision, the Board denied Wright's request that it modify its original decision.
Footnote 3. Transfection, infection, genetic recombination, and viral replication collectively constitute a procedure known as marker rescue.
Footnote 4. The allowed claims read:

Claim 13 A live, non-pathogenic vaccine for a pathogenic RNA virus, comprising an immunologically effective amount of a viral, antigenic, genomic expression having an antigenic determinant region of the RNA virus, but no pathogenic properties, the viral, antigenic, genomic expression being the RAV-Acn virus.

Claim 14 A vaccine according to claim 13, wherein the vaccine has been purified by selection for the expression of the antigenic genome.

Claim 43 A process for producing a live, non-pathogenic, recombinant vaccine conferring immunity against the PrASV avian tumor virus in chickens, comprising inserting the PrASV env A gene into a RAV-O virus by marker rescue such that said PrASV env A gene replaces the endogenous envelope gene of the RAV-O virus; and selecting for the recombinant in C/E cells.

Claim 44 A live, non-pathogenic, recombinant vaccine conferring immunity against the PrASV avian tumor virus in chickens, in which vaccine the PrASV env A gene has been inserted into a RAV-O virus by marker rescue to replace the endogenous envelope gene of the RAV-O virus, and the recombinant has been selected for in C/E cells.

Footnote 5. The Board stated in its opinion that it was affirming the Examiner's rejection under section 112 for the reasons set forth in the Examiner's Answer and that the Board's added comments were for emphasis only.

Footnote 6. Wright defines "vaccine" at page 1 of his specification as being a "material which induces an organism to acquire immunity against disease." Furthermore, as noted by the Board, the *Dictionary of Biochemistry* 330 (John Wiley & Sons 1975), defines "vaccine" as a suspension of antigens derived from viruses or bacteria that, upon administration, will produce active immunity and provide protection against those viruses or bacteria or related viruses or bacteria.

Footnote 7. *See* Shio-Luk Hu et al., *Protection of Macaques Against SIV Infection by Subunit Vaccines of SIV Envelope Glycoprotein gp160,* 255 Science 456-59 (1992); Shio-Luk Hu et al., *Neutralizing Antibodies Against HIV-1 BRU and SF2 Isolates Generated in Mice Immunized with Recombinant Vaccinia Virus Expressing HIV-1 (BRU) Envelope Glycoproteins and Boosted with Homologous gp 160,* 7 AIDS RESEARCH AND HUMAN RETROVIRUSES 616-20 (1991); Phillip W. Berman et al., *Protection of Chimpanzees from Infection by HIV-1 after Vaccination with Recombinant Glycoprotein gp120 but not gp160,* 345 Nature 622-625 (1990).

Footnote 8. In his appeal to this court, Wright all too frequently slips into using the present tense to discuss the state of the art and what a skilled artisan would believe given Wright's success with one avian virus. We note, however, that the issue is not what the state of the art is today or what a skilled artisan today would believe, but rather what the state of the art was in February of 1983 and what a skilled artisan would have believed at that time. *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir.), *cert denied,* 480 U.S. 947 (1987); *In re Hogan,* 559 F.2d 595, 604, 194 USPQ 527, 535 (CCPA 1977). Wright's tendency to employ the present tense often makes it difficult to determine whether Wright is asserting that certain information was known prior to February of 1983 or simply that that information is now known in the art.

Footnote 9. For example, O'Neill stated in his affidavit that the specification provided him "with sufficient information to produce a vaccine for any known pathogen in accordance with the procedural steps claimed" and that he could not "foresee any problem in producing similar vaccines for other pathogens." Bennett and Burnett merely declared in their affidavits that, at the time they worked with Wright, they believed that the specific vaccine that they were developing was simply one example within a broader concept. In his October 22, 1984 declaration, Wright stated that he knew "of no reason why the specific vaccine tested is not truly indicative of successful application of other embodiments of the invention within the purview of the teachings and claims of my

patent application." Wright further stated that " [although the project has been primarily directed toward the production and testing of a specific vaccine for a specific virus, the concept has been inherently generic as claimed."
Footnote 10. The paper states in pertinent part: "Recent observations suggest line SC chickens do not respond well immunologically. . . . Follow up experiments will include other chicken lines. Mechanisms of protection are also under study."

- End of Case -

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Serial No. 09/438,206
Group No. 1617
Confirmation No. 9018

In re Kerkhoven

(CCPA)
205 USPQ 1069

Decided May 15, 1980
No. 79-586
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability -- Composition of matter (§ 51.30)

Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)

It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, claims that require no more than mixing together of two conventional spray-dried detergents set forth prima facie obvious subject matter.

2. Patentability -- Composition of matter (§ 51.30)

Patentability -- Evidence of -- Comparison with allowed claims or patents (§ 51.457)

Comparative test data that is not commensurate with claims' scope offered as evidence of superiority of claimed method does not rebut prima facie case of obviousness.

3. Patentability -- Composition of matter (§ 51.30)

Patentability -- Invention -- In general (§ 51.501)

Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)

Patentability -- New use or function -- Nonanalogous art (§ 51.557)

Problem of how to introduce more than one color into detergent and problem of how to improve flow characteristics of mixed-active detergent are quite remote; mere knowledge that simultaneous spray-drying multiple slurries was useful technique in production of multi-colored detergents would not have suggested anything about effect of simultaneous spray-drying slurries having different active detergent contents, one being primarily if not exclusively anionic in nature and other being primarily if not exclusively nonionic in nature, on flow characteristics of final mixed-active product; claimed process, considered as a whole, as required by 35 U.S.C. 103, would not have been prima facie obvious to one skilled in art at time invention was made where one skilled in art working at that time on problem invention solved would not have been motivated or guided by prior art to arrive at claimed process.

Particular patents -- Detergent

Kerkhoven, Production of Detergent Compositions, rejection of claims 2-4, 9, and 14 affirmed; rejection of claim 5 reversed.

Case History and Disposition:

Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of Frederik Johan Kerkhoven, Serial No. 501,956, filed Aug. 30, 1974. From decision rejecting claims 2-5,

9, and 14, applicant appeals. Modified; Miller, Judge, with whom Markey, Chief Judge, joins, dissenting in part with opinion.

Attorneys:

James J. Farrell, Edgewater, N.J., for appellant.

Joseph F. Nakamura (Gerald H. Bjorge, of counsel) for Commissioner of Patents and Trademarks.

Judge:

Before Markey, Chief Judge, Rich, Baldwin, and Miller, Associate Judges, and Newman, * Judge.

 ISSN 1526-8535

Opinion Text

Opinion By:

Newman, Judge.

This is an appeal from the decision of the United States Patent and Trademark Office (PTO) Board of Appeals (board) sustaining the examiner's rejection under 35 USC 103 of claims 2-5, 9 and 14 of application serial No. 501,956, filed August 30, 1974, for "Production of Detergent Compositions." We modify.

Background

The Invention

Appellant claims a process for the production of particulate detergent compositions containing a mixture of anionic [1] and nonionic [2] active detergent materials. Appellant explains in his specification that the detergent-making art often prefers such detergents to achieve optimal detergent properties, and he notes that the most commonly used active detergent combination is a mixture of anionic fatty acid soaps, anionic synthetic non-soap detergents, and nonionic detergents. Detergents made from this combination of ingredients are called mixed-active detergents.

Appellant's invention is generic in the sense that it covers two separate and distinct methods of producing mixed-active particulate detergents, each method including the common step of forming at least two slurries [3] of detergent ingredients, the active detergent content of one slurry being primarily if not exclusively anionic in nature and the active detergent content of the other slurry being primarily if not exclusively nonionic in nature. Under one of these methods, the slurries are independently dried and the resulting products are mixed. Under the other method, the slurries are simultaneously dried and mixed.

Appealed claims 2-4, 9 and 14 are drafted broadly enough to cover both of these modes of operation. Claim 14 is illustrative:

> 14. A process for preparing a spray-dried detergent composition comprising by weight 5-80% of builders, 0-50% fillers and 5-60% of active detergent materials consisting essentially of a mixture of 20-80% by weight of anionic detergents of which 10-90% by weight is a fatty acid soap, and 80-20% by weight of nonionic detergents, which process comprises forming approximately equal proportions of at least two aqueous slurries A and B, slurry A being composed of a builder slurry incorporating therein an active detergent component consisting essentially of 60-100% by weight of anionic detergents and 0-40% by weight of nonionic detergents, slurry B being composed of a builder slurry incorporating therein an active detergent component consisting essentially of 0-40% by weight of anionic detergents and 60-100% by weight of nonionic detergents, treating said slurries as separate streams in at least on spray-drying equipment and collecting/mixing the dried products to form a homogeneous mixture of particulate material comprising said detergent composition.

Appealed claim 5, however, is limited to only the simultaneously dry and mix method. Claim 5 reads as follows:

> 5. A process according to claim 14, in which slurries A and B are spray-

dried simultaneously in one spray-drying tower through separate nozzle systems, having points of entry on the tower at substantially equal height level of the tower.

According to appellant, the conventional manner of making mixed-active particulate detergents had been to mix all of the ingredients together in one slurry and then spray-dry the slurry. Appellant alleges that this single-slurry technique produces detergents having poor flow characteristics, whereas his multi-slurry methods produce detergents having excellent flow characteristics.

To prove this, appellant conducted tests comparing the flow characteristics of detergents made by these processes. The results from these tests show that mixed-ac

tive detergents made according to both of the claimed multi-slurry methods had good flow characteristics. On the other hand, detergents comprising the same ingredients made by the above-described single-slurry process had poor flow characteristics. The tests, however, did not compare the flow characteristics of compositions containing partially prehydrated sodium tripolyphosphate builder.

The Prior Art

The PTO has cited the following references as prior art:

Coffey [4] describes a process for the production of mixed-active particulate detergents having good flow characteristics. Coffey uses a single slurry technique, i.e., all the ingredients are mixed together in one slurry which is then spray-dried. According to Coffey, his detergents have good flow characteristics because he includes in the slurry partially prehydrated sodium tripolyphosphate builder.

Cavataio [5] and Tofflemire [6] disclose processes for the production of multicolor particulate detergents. The multi-color effect is achieved by simultaneously spray-drying a natural colored detergent slurry and a colored detergent slurry through separate nozzles in the same spray-drying tower. In Tofflemire, the nozzles are at the same height in the tower.

Colgate [7] teaches mixed-active detergents having enhanced soil-suspending properties. The flow characteristics of these detergents are not discussed.

Ruff [8] discloses anionic spray-dried detergents and nonionic spray-dried detergents having tarnish inhibiting properties.

Examiner's Rejection

The examiner rejected all of the appealed claims under 35 USC 103 as unpatentable either over Cavataio in view of Colgate, Coffey, Ruff and Tofflemire, or over Colgate and Coffey in view of Cavataio, Ruff and Tofflemire. He explained that the claims require no more than the mixing of two conventional spray-dried detergent compositions, and concluded that the mere mixing of two compositions each taught for the same purpose, in the absence of a showing of unexpected results, is obvious. In support of this proposition, the examiner cited In re Crockett, 47 CCPA 1018, 279 F.2d 274, 126 USPQ 186 (1960).

The examiner determined that appellant had not demonstrated any unexpected

advantage for the claimed process. He pointed out that although the claims encompass the use of prehydrated sodium tripolyphosphate builder, appellant had not shown that the product produced from his process was superior to that obtained from Coffey's process, when prehydrated sodium tripolyphosphate was used. The examiner also noted that appellant had not demonstrated that Colgate's product had poor flow characteristics.

In his original rejection, the examiner did not comment on the independent patentability of claim 5. However, in the examiner's Answer to appellant's brief before the board, the examiner acknowledged that claim 5 presented the additional issue of whether it would be obvious to spray dry the two compositions simultaneously in one tower through separate nozzles at an equal height level. The examiner concluded that this would have been obvious, reasoning:

> Appellant has neither argued nor demonstrated that this method of simultaneous spray drying in a single tower provides any unexpected results. Further, this process would be suggested by the teachings in Tofflemire and appellant's admission in the sentence bridging pages 27 and 28 of his brief that "given the long standing practice of spray drying with a multiplicity of nozzles, the *possibility* of introducing separate streams to any or all of these separate nozzles would be obvious to anyone of ordinary skill in the art". [Emphasis in original.]

Appellant responded to this point in his reply brief before the board with the following:

> The Examiner's arguments with respect to claim five, that applicant has

> admitted the possibility of introducing separate streams to any or all of separate nozzles as being obvious, does not relate to whether one skilled in the art would actually do such a thing without applicant's teaching. Indeed to argue the impossibility of introducing separate slurries to separate nozzles and spray drying them simultaneously would be fruitless.
>
> Tofflemire is directed to producing a multicolored particulate detergent and has nothing to do with combining two slurries such as applicant has claimed.

Board's Rejection

The board affirmed the examiner's rejection adding that in its opinion one skilled in this art, knowing that individual detergents or certain mixtures of detergents produce particles having good free-flow characteristics, would understand that the detergents desired in the final composition may be dried separately and then mixed. The board did not address the issue of the independent patentability of claim 5.

Appellant's Argument

Appellant contends that there is no suggestion in the prior art to split the active detergents into two specific slurries and spray-dry them either simultaneously to obtain a final product or separately and then mix them to obtain a final product. Therefore, appellant argues, no prima facie case of obviousness exists, and a showing of unexpected results is not required.

Appellant maintains that, as was the case in In re Sponnoble, 56 CCPA 823, 405 F.2d 578, 160 USPQ 237 (1969), appellant's invention here is the discovery of the source of a

problem and the finding of a solution for that problem. Appellant points out that none of the cited references except Coffey recognized the problem here. and that Coffey employed a different route to solve it.

Appellant notes that claim 5 which calls for simultaneous spray-drying is even more remote from the examiner's references than the other appealed claims. Appellant submits that the process of claim 5 would not be performed by the mere mixing of two known spray-dried detergents.

Solicitor's Argument

The solicitor asserts that one of ordinary skill in the art -- faced with the problem of poorly flowing mixed-active detergents prepared by spray-drying one slurry containing all detergents, and armed with the knowledge that detergent compositions do not present such difficulties if the active detergent component is not a mixture of different active detergents -- would readily understand that the detergents desired in the final composition may be dried separately and then mixed. He submits that the problem and its source were known, and that the solution thereto claimed herein would have been obvious.

In his brief, the solicitor does not address the issue of the independent patentability of claim 5. When asked to comment on the rejection of claim 5 at oral argument, the solicitor stated that the basis for the PTO's case of obviousness for claim 5 was: (1) appellant's description of the prior art before the board, wherein appellant stated that Cavataio makes detergent compositions by spray drying two detergent slurries of different chemical composition simultaneously in a tower; (2) the disclosure in Tofflemire that shows the feature of simultaneous spray-drying two slurries from the same height in a spray-drying tower; and (3) appellant's admission that simultaneous spray-drying of two detergent slurries was known.

Opinion

[1] It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art. In the case at bar, appealed claims 2-4, 9 and 14 require no more than the mixing together of two conventional spray-dried detergents. Thus, these claims set forth prima facie obvious subject matter.

[2] The comparative test data offered by appellant as evidence of the superiority of this claimed method does not rebut the prima facie case of obviousness because it is not commensurate in scope with the claims. The claims are broad enough to cover multi-slurry-produced detergent compositions containing partially pre-hydrated sodium tripolyphosphate builder. Coffey teaches that single-slurry-produced detergent compositions containing this builder have good flow characteristics. Appellant's attorney admits that appellant has not run any tests comparing his multi-slurry-produced

detergent compositions containing this builder with Coffey's single-slurry-produced

detergent compositions containing this builder. Thus, appellant has failed to prove the superiority of his multi-slurry technique over the prior art's single-slurry technique for the production of detergent compositions containing this builder. Having failed to do this, appellant has not proven the superiority of the multi-slurry technique over the single-slurry technique for all compositions covered by the claims.

Claim 5

In review of this application, the board lumped claim 5 together with the rest of appellant's claims. Appellant specifically objects to this treatment -- and we agree.

Claim 5 sets forth an alternative process for making a mixed-active spray-dried particulate detergent. Whereas the other claims on appeal include in their coverage the process of merely combining a known anionic spray-dried particulate detergent with a known nonionic spray-dried particulate detergent to form a mixed-active particulate detergent product, claim 5 is limited to the process of making a mixed-active particulate detergent product by simultaneously spray-drying through separate nozzle systems in one spray-drying tower one detergent slurry, having an active detergent content of 60-100% anionic and 0-40% nonionic, and another detergent slurry having an active detergent content of 60-100% nonionic and 0-40% anionic.

Searching the references, we find no support for the PTO's prima facie case of obviousness for claim 5. Coffey, the only reference which describes a prior art method for obtaining good-flowing mixed-active particulate detergents, does not use simultaneous spray-drying, but rather teaches a single-slurry technique that requires partially pre-hydrated sodium tripolyphosphate builder.

Coffey explains that it was an object of his invention "to enable the production of satisfactory detergent compositions comprising appreciable proportions of [nonionic active detergent ingredients]." According to Coffey, "it [had] not been readily possible, [prior to Coffey's invention], to make acceptable detergent compositions in powdered or granular form incorporating appreciable quantities of [nonionic active detergent ingredients], * * *, as such compositions [were] sticky and [had] poor flow properties rendering their production and packaging difficult and so making them unsatisfactory for commercial use." Coffey discloses, however, that under his invention: "Such compositions may be made with good flow properties and texture which are retained during storage, * * *." The "essential feature" of Coffey's method for making satisfactory mixed-active detergent compositions is the use of partially pre-hydrated sodium tripolyphosphate builder.

Unlike Coffey's method, appellant's process (claim 5) for making a mixed active detergent with good flow characteristics does not rely on partially pre-hydrated sodium tripolyphosphate builder. Rather, appellant solves this flow problem by utilizing the technique of simultaneously spray-drying through separate nozzle systems in one spray-drying tower one detergent slurry having an active detergent content that is primarily if not exclusively anionic and another detergent slurry having an active detergent content that is primarily if not exclusively nonionic. Although simultaneous spray-drying of multiple slurries did not originate with appellant, on this record he appears to have been the first to utilize this technique with slurries having different active detergent contents, one being primarily if not exclusively anionic in nature and the other being primarily if not exclusively nonionic in nature, in order to improve the flow characteristics of the

final mixed-active product.

[3] In the past, simultaneous spray-drying of multiple slurries was limited to the production of multicolor detergents wherein the specific active detergent content of the slurries was beside the point. [9] We conclude that the problem of how to introduce more than one color into a detergent and the problem of how to improve the flow characteristics of a mixed-active detergent are quite remote. Mere knowledge that simultaneous spray-drying multiple slurries was a useful technique in the production of multi-colored detergents would not have suggested anything about the effect of simultaneous spray-drying slurries having different active detergent contents, one being primarily if not exclusively anionic in

nature and the other being primarily if not exclusively nonionic in nature, on the flow characteristics of the final mixed-active product. Consequently, one skilled in this art, working at the time appellant's invention was made on the problem of how to obtain good flow characteristics in mixed-active spray-dried detergents without resort to partially pre-hydrated sodium tripolyphosphate builder, would not have been motivated or guided by the prior art to arrive at the process appellant is claiming in claim 5, that is, a process for making a mixed-active detergent wherein the flow characteristic problem is solved by resort to the simultaneous spray-drying technique heretofore only used in the production of multi-colored detergents. For this reason, we hold that the process described in claim 5, considered *as a whole* as required by 35 USC 103, would not have been prima facie obvious to one skilled in the art at the time this invention was made. Cf. In re Sponnoble, 56 CCPA 823, 405 F.2d 578, 160 USPQ 237 (1969); In re Kuehl, 475 F.2d 658, 177 USPQ 250 (CCPA 1973).

Accordingly, the decision of the board is *affirmed* with regard to claims 2-4, 9 and 14, and *reversed* as to claim 5.

Modified.

Footnotes

Footnote 1. An anionic substance is one which is negatively charged.
Footnote 2. A nonionic substance is one which is electrically neutral, that is, it does not have either a positive or negative charge.
Footnote 3. A slurry is a watery mixture or suspension of insoluble matter.
Footnote 4. Canadian patent to Coffey, Griffiths, and Naylor, No. 852173, issued September 22, 1970, for "Process for the Production of Detergent Compositions."
Footnote 5. U.S. patent to Cavataio and Monick, No. 3,519,054, issued July 7, 1970, for "Process for Producing a Particulate Product."
Footnote 6. U.S. patent to Tofflemire, No. 3, 357,476, issued December 12, 1967, for "Process and Apparatus for Spray Drying Multi-Colored Detergent Particles."
Footnote 7. British patent specification of Colgate-Palmolive Company, No. 931,438, published July 17, 1963, for "Solid Detergent Composition."
Footnote 8. U.S. patent to Ruff, No. 2,861,954, issued November 25, 1958, for

"Polyphosphate Compositions Containing Soap and 2-Mercaptothiazoline."
Footnote 9. Although Cavataio implies that the colored slurry could be different from the matrix slurry composition-wise, nowhere does he teach or even hint at the particular difference here claimed, i.e., that the slurries have different active detergent contents, one being primarily if not exclusively anionic in nature and the other being primarily if not exclusively nonionic in nature. In point of fact, Cavataio's only illustration of this point is an example wherein one slurry contains none of the active detergent material.

Dissenting Opinion Text

Dissent By:

Miller, Judge, with whom Markey, Chief Judge, joins, dissenting in part.

I cannot agree that the rejection of claim 5, which requires simultaneous spray-drying and mixing of two conventional detergent slurries, should be reversed. The majority opinion recognizes that the motivation for one of ordinary skill in the art to mix the dried detergents together after independent spray-drying follows logically from the prior art. In re Susi and In re Crockett, both cited in the majority opinion. Nevertheless, it concludes that mixing them during *simultaneous* spray-drying would have been beyond the level of ordinary skill in the detergent-making art, even though, as the majority opinion recognizes, simultaneous spray-drying of multiple slurries is a conventional process in that art. [1]

How or why such mixing would have been beyond the level of ordinary skill in the art is not explained except by the statement that there would have been no motivation therefor, because the prior art simultaneous spray-drying technique had only been used in the production of multicolored detergents. However, this position is untenable, because Cavataio et al. teach that two detergent slurries to be simultaneously spray-dried can be of *different compositions* as well as of different colors. [2] Thus, motivation to use *any* two conventional slurries (having different active detergent contents) in the Cavataio et al. process would have been provided one of ordinary skill in the art, and a prima facie case of obviousness is established.

The majority opinion's reversal of the rejection of claim 5 clearly relies upon its conclusion that appellant "solves this flow problem" (the "sticky and poor flow properties" of detergent compositions related by Coffey), accepting as fact that appellant's process produces detergents "with good flow characteristics." However, in affirming the rejection of all the other claims, the majority opinion does not accept appellant's "good flow characteristics" test data as sufficient to rebut a prima facie case of obviousness. Moreover, it does not necessarily follow that a product possessing nonobvious properties renders a process for making that product nonobvious. As Judge Rich explained in his concurring opinion in In re Larsen, 49 CCPA 711, 716-17, 292 F.2d 531, 534-36, 130 USPQ 209, 212-13 (1961):

> [I]f it be the fact that the final compound AB possesses unique, unexpected, surprising, or highly useful properties, they *inhere in the product* AB, not in A alone, B alone, *or in the process* of reacting them. While such attributes in a

> product may make it, the product, patentable they do not make the process patentable because they are in no way a part of the process. * * *
>
> There is a certain amount of logic in holding a product to be unobvious

> because of the discovery in it of unobvious properties * * *. But I see neither logic nor sound interpretation of the patent law in transferring such properties from the product in which they inhere to a process of making the product in which they do not.

See In re Hoeksema, 51 CCPA 1474, 1478, 332 F.2d 374, 377, 141 USPQ 733, 735-36 (1964), pointing out:

> In In re Larsen * * * this court held a process to be obvious although it produced a product which, because of its unexpected properties, was unobvious.

See In re Kuehl, 475 F.2d 658, 665, 177 USPQ 250, 255-56 (1973), in which the unanimous opinion by Judge Roth points out that "each statutory class of claims must be considered independently on its own merits" and that "an applicant does not get such [process] claims just because the product is new and unobvious." Appellant's citation of In re Sponnoble, 56 CCPA 823, 405 F.2d 578, 160 USPQ 237 (1969), is not apt, because the appealed claim with a limitation directed to the solution of a problem.

Although the manufacture of detergents may involve chemical reactions in process steps, claim 5 involves merely the physical process of simultaneously spray-drying two known slurries, and there is no indication that a chemical reaction occurs in the spray-drying tower. Accordingly, the uncertainty and unpredictability often associated with the chemical arts is not present here.

With respect to appellant's claim limitation that the nozzles be located at a "substantially equal height level of the tower," Cavataio et al. disclose that the point of entry of the second liquid can be as close as 15% "below the level of the point of entry of the first liquid, the percentage based on the distance from the bottom of the spray tower to the point of entry of the first liquid." Moreover, the Tofflemire reference (U.S. Patent 3,357,476) expressly discloses the simultaneous spray drying of two different detergents (one colored, the other not colored) at the same height.

I would hold that the Patent and Trademark Office has established a prima facie case of obviousness of claim 5 and that this has not been rebutted by appellant's comparative test data, the same not being commensurate in scope with the claim, as clearly pointed out in the majority opinion.

Footnotes

Footnote 1. The majority opinion says that appellant appears to have been the first to utilize simultaneous spray-drying with slurries having different active detergent contents, but, at oral argument, counsel for appellant stated that it made no difference whether the compositions were separately dried before mixing or simultaneously dried and mixed.

Footnote 2. Cavataio et al. state that "both the matrix and the contrasting colored liquid are in the form of slurries which contain the necessary components for a complete

detergent composition." The majority opinion offers no reason for limiting this teaching of Cavataio et al. to the specific slurry compositions used in their several examples.

Footnote * The Honorable Bernard Newman, United States Customs Court, sitting by designation.

- End of Case -